MAMMOGRAM AND ULTRASOUND EVALUATION OF BREAST LESIONS WITH FNAC CORRELATION

Dissertation

Submitted to

THE TAMILNADU Dr. M.G.R MEDICAL UNIVERSITY

In partial fulfilment of the requirements for

the award of the degree of

M.D RADIODIAGNOSIS

BRANCH VIII

APRIL 2017

CERTIFICATE

This is to certify that this dissertation entitled **"Mammogram and Ultrasound Evaluation of Breast Lesions with FNAC Correlation"** is a bonafide record of the work done by **Dr. Mahtab Yeganegi** under guidance and supervision in the Department of Radiodiagnosis during the period of her postgraduate study for **M.D Radiodiagnosis [Branch-VIII]** from 2014-2017.

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DECLARATION

In the following pages is presented a consolidated report of the study **"Mammogram and Ultrasound Evaluation of Breast Lesions with FNAC Correlation"** a cross sectional study, on cases coming to Radiodiagnosis outpatient Department at Sree Mookambika Institute of Medical Sciences, Kulasekharam from 2015-2016. This thesis is submitted to the Dr. M.G.R. Medical University, Chennai in partial fulfilment of the rules and regulations for the award of MD Degree examination in Radiodiagnosis.

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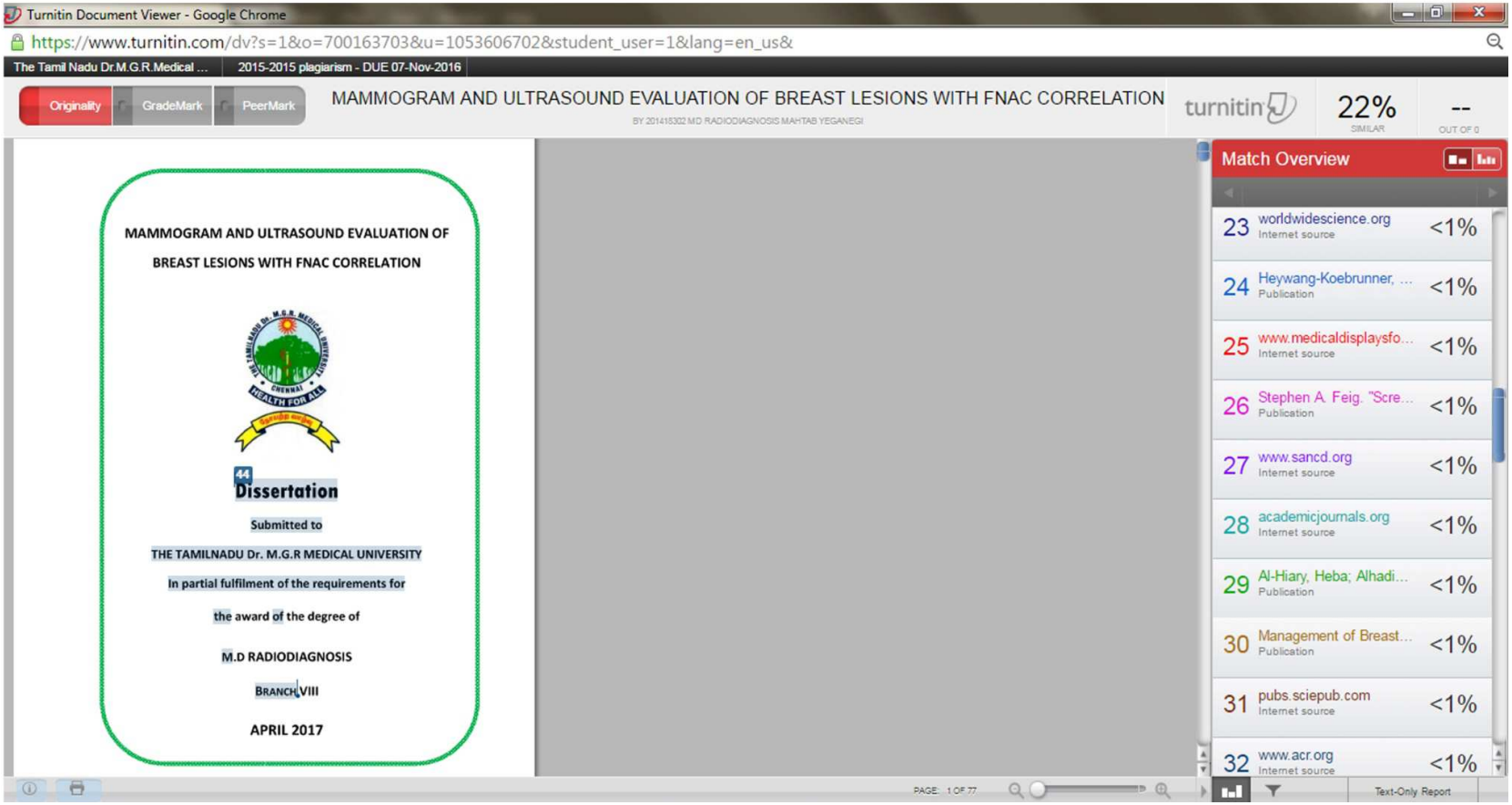
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Dr. Mahtab Yeganegi

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Introduction

INTRODUCTION

Only 6.3 million women of the total number of cases diagnosed with breast cancer in the past five years were alive, whereas in the year 2012, 1.7 million were diagnosed with breast cancer. Its incidence since 2008 has risen by more than 20%, whereas there has been an increase of 14% in the mortality incidence. One of the most common causes of cancer related death among women is breast carcinoma accounting to approximately 522 000 in the year 2012. In 140 of 184 countries worldwide it is the most frequently diagnosed cancer among women which now represents one in four of all cancers in women.[1, 2]

One of the leading cause of cancer death in the less developed countries of the world is breast cancer. This is partly because of clinical advances to combat the disease which are not reaching the women living in those regions and also because of a shift in lifestyle, which is causing an increase in its incidence.[1]

All detected breast lesions are not malignant and all the benign masses do not progress to cancer; nevertheless the precision of the final diagnosis can be greatly increased by radiological imaging (mammography, ultrasonography) and pathological diagnosis.[3]

The present study is to evaluate the breast lesions according to BI-RADS (Breast Imaging Reporting and Data System) by using two different radiological procedures (non-invasive method) with correlation of FNAC (invasive method).

Aims & Objectives

AIMS AND OBJECTIVES

1. To study the mammographic and ultrasonographic characteristics of breast lesions in patients.
2. To categorize the detected breast lesions according to BI-RADS.
3. To correlate the categorized breast lesions (BI-RADS) with FNAC.
4. To compare the sensitivity of mammography with ultrasonography in diagnosing benign and malignant breast lesions.

Hypothesis & Scientific Justification

HYPOTHESIS AND SCIENTIFIC JUSTIFICATION

HYPOTHESIS:

The null - hypothesis stated that mammography and ultrasonography had specificity and sensitivity similar to FNAC, in the detection of breast lesions (BI-RADS).

SCIENTIFIC JUSTIFICATION OF THE STUDY:

Early detection and improved treatment is required to decrease breast cancer related deaths. The effective diagnosis and management of breast lesions involves multidisciplinary approach to their assessment. Non-invasive techniques such as mammography, is a well-defined and widely accepted radiologic procedure to evaluate clinically suspected breast lesions and as a tool to screen for breast cancer. However, the appearance of overlapping tissue on mammograms poses a significant obstacle to interpretation. Hence, ultrasonography is an adjunctive modality, especially in patients with dense breasts and it also helps to characterize an undetected abnormality on mammography. Combining both the modalities (mammography and ultrasonography) yielded the best results. Ultrasonography and mammography diagnosed lesions, were confirmed by FNAC. As FNAC is an invasive procedure, imaging modalities that can detect and grade the lesion according to BI-RADS, will reduce the requirement of subjecting the patient to invasive procedures especially in definitively benign lesions.[1, 2]

Review of Literature

REVIEW OF LITERATURE

PREVALENCE OF BREAST CARCINOMA

Breast cancer is the second most common cancer in India, (after cervical cancer) with an approximate of 115,251 new diagnoses. It is the second most common cause of cancer-related deaths with 53,592 deaths in 2008.[2]

Phurailatpam et al. conducted a study on evaluation of breast lesions on mammography, ultrasonography and by correlating with Fine Needle Aspiration Cytology at Sri Devaraj URS Medical College & Research Centre, Tamaka, Kolar, Karnataka. 75 patients attending the OPD were included in the study during a period of January 2012-August 2013. The patients were subjected to both mammography and ultrasonography and then diagnosed with FNAC. Mammographic diagnosis with FNAC: Sensitivity - 92.3% Specificity – 91.8%. Comparison of ultrasonography diagnosis with FNAC: Sensitivity – 80.1 % Specificity – 100%. Comparison of diagnosis by combined imaging modalities with FNAC: Sensitivity – 92.3 % Specificity – 100 %.[4]

Shetty et al. conducted a study of 411 patients with palpable breast abnormalities. One hundred sixty-five (40.1%) of 411 palpable abnormalities had a benign assessment; both mammography and ultrasonography revealed 97 among those 165 patients, 66 (40%) of 165 benign lesions were mammographically occult and they were seen in ultrasonography. Nineteen (31.6%) of the 60 lesions which were considered suspicious and was mammographically occult was identified only on ultrasonography. The sensitivity (14 of 14) and negative predictive value

(186 of 186) for a combined assessment with mammography and ultrasonography was 100% and the specificity was 80.1%.[5]

In the series of Kolb et al., in women with heterogeneously dense or dense breasts, ultrasonography alone was once again seen to be much more sensitive than mammography; with 60 (57%) of 105 of cancers seen mammographically and 83 (79%) of 105 seen ultrasonographically. The combination of ultrasonography and mammography depicted 101 (96%) of 105 of cancers in this group.[6]

Taori et al. conducted a study by using Mammography and Ultrasonography as the first line of investigation on evaluating breast masses at Government Medical College, Nagpur, India. 166 female patients complaining of breast masses were included in the study period December 2010 to December 2012. Out of a total of 92 abnormal breast masses, 12 of them were missed on ultrasonography and the rest of the masses were missed on mammography. Combined sonomammography, the number of lesions that were missed was 2. Combining both the modalities the specificity was 97.6% and the individual specificity for USG 86.9% and for mammography it was 78.6%. [7]

Devolli-Disha et al. study included 546 patients with breast lesions. The study observation showed that density indicated that mammographic sensitivity was 82.2% among women with predominantly fatty breast, and it was a meagre value of 23.7% in women with heterogeneously dense breast

tissues. Increase in fibro glandular density, decreased the level of sensitivity with mammography, while ultrasonographic sensitivity was 71.1% among women with mainly fatty breast and 57.0% for heterogeneous dense breasts.[8]

Leconte et al. study included 4236 patients to detect the nonpalpable breast cancers who underwent dual imaging which included USG and mammogram..Sensitivities of mammography and ultrasonography for detecting non-palpable breast cancers were 80% and 88% in grades 1 and 2, and 56% and 88% in grades 3 and 4 breasts.[9]

Table 1. Advantages and limitations of Ultrasonography[7]

Advantages	Limitations
To detect the type of lesion - cystic or solid and contents within (echoes, debris, septae)	Fairly well-defined malignant masses can be labelled benign
Better used in tender breast and infective condition.	The lesion can be obscured by fat and air.
Dense breasts are evaluated better	Microcalcifications can be missed
No radiation exposure, better in pregnancy and lactation	Sensitivity depends on operator
It is real time and whole breast region can be evaluated even in large breast.	Multicentric lesion and isoechoic lesions can be missed
Vascularity can be commented	
Flat bony lesions and mimics of the breast masses can be evaluated	

Table 2. Advantages and limitations of Mammography[7]

Advantages	Limitations
Better in detection of spiculated masses	Solid and cystic masses cannot be differentiated
Better detection of microcalcification	Not done in lactation and pregnancy
Multiple lesions can be better made out with relation to each other	Sensitivity decreases in dense breast & breast infections
Sterotactic biopsy can be done.	Not done in very painful tender breast
	Not done in flat masses and mimics of breast masses (bony or pleural lesions)
	Complete visualization of the breast is not possible in any single view
	Very large breasts could not be evaluated adequately

AMERICAN COLLEGE OF RADIOLOGY BREAST IMAGING REPORTING AND DATA SYSTEM [10]

A guideline has been established by The American College of Radiology (ACR) for the diagnosis of breast cancer called - the Breast Imaging Reporting and Data System (BI-RADS). The BI-RADS system is intended to guide radiologists and the physicians referring the cases in the

decision-making process which will ultimately help the patient by planning for better patient care. To standardize the interpretation of mammogram and ultrasonography among radiologists, the BI-RADS system was introduced. BI-RADS assessment categories can be summarized as given below:

Category 0 - Needs further evaluation (by imaging)

Category 1 - Negative

Category 2 - Benign finding, noncancerous

Category 3 - Probably benign finding, suggest: short-interval follow-up

Category 4 - Suspicious abnormality, biopsy considered.

Category 4A: Low suspicion for malignancy

Category 4B: Moderate suspicion for malignancy

Category 4C: High suspicion for malignancy

Category 5 - Features are highly suggestive of malignancy, appropriate action needed.

Category 6 - Known - Biopsy proven carcinoma.

Wendie A. Berg et al. conducted a study for preoperative assessment of breast cancer by evaluating clinical examination, diagnostic accuracy of Mammography, USG and MR Imaging. Results of all three imaging modalities from 111 women giving a history of having known a history breast carcinoma or suspected with having invasive breast carcinoma were analyzed. Results obtained were correlated with histopathologic findings. In dense

breasts, USG and MRI were much more sensitive than mammography for invasive carcinoma, but there was the risk of overestimation the tumour extent by both imaging modalities. Combined clinical examination with mammogram and MRI was the most sensitive method.[11]

Oswald Graf, MD et al. conducted a study to determine whether palpable non-calcified solid breast masses with benign morphology at mammography and ultrasonography (USG) can be managed in the same way as a non-palpable, probably benign lesions — i.e., with regular imaging follow-up and to determine whether biopsy can be avoided in these lesions. In 102 (94.4%) of 108 patients, the breast lesions remained the same during follow-up evaluation. For at least 2 years, the lesions were followed up. The palpable lesions increased in size during follow-up in 6 of the patients which turned out to be benign at open biopsy. 44 of the 45 patients with palpable lesions who underwent biopsy after initial imaging were not diagnosed with breast carcinoma. The results obtained suggested that noncalcified, palpable solid breast masses with benign morphology at mammography and USG can be managed similarly to non-palpable BI-RADS 3 lesions, with 6 month intervals follow-up for 2 years.[12]

Mark A.D. et al. had conducted a study on the value of normal mammogram and normal ultrasonography in a palpable breast lump and to avoid unnecessary breast biopsy. No patient in the non biopsy group developed carcinoma at the initial site of concern during a mean

mammographic and clinical follow-up period of 43 months, and all biopsy specimens were benign (negative predictive value,100%).[13]

Sabine Malur et al. conducted a study in which patients with breast lesions (n=413) were examined by imaging modalities (mammography, ultrasonography and MRI); showed 185 invasive carcinoma, 38 were found to be carcinoma in situ and 254 of the lesions were benign tumours which were pathologically diagnosed. For invasive cancers the sensitivity for each imaging modality was as follows: mammography (83.7%), ultrasonography (89.1%) and for MR mammography (94.6%). Patients who had invasive cancers in multiple areas were 42 which had been detected by combination of mammography and ultrasonography in 26.2% and by MRI mammography alone in 66.7%. Carcinoma in situ was diagnosed by mammography in 78.9% and 68.4% of patients by MR mammography. In conclusion to yield the best results for detection of invasive cancer and multifocal disease, combination of all three diagnostic methods should be used.[14]

Harmine. M. Zonderland et al. had conducted a study to determine the use of ultrasonography as an added imaging modality to the routine mammography imaging for the diagnosis of breast cancer. In 338 cases, breast cancer was diagnosed. The specificity of mammography improved when used in combination with USG. It was found that the increase in sensitivity was highest among women younger than 50yrs. The use of

USG as an add-on to mammography resulted in a better diagnostic accuracy.[15]

Luciano Chala et al. did a retrospective on 229 females with breast masses and found the following features to favour benignity of a lesion. These include the lesion being round, ellipsoid, or lobulated masses with 3 or fewer lobulations, a longitudinal–anteroposterior diameter ratio > than or =1.0 circumscribed margins and no marked hypoechogenicity, posterior acoustic shadowing, internal microcalcifications, or altered surrounding breast tissue.[16]

In 2000, Sara M.Durfee et al. retrospectively reviewed the pathological database to identify patients who had palpable abnormalities and consecutive patients who had undergone excision. Both mammogram and breast ultrasound were compared with pathological and surgical findings and concluded that patients presenting with a breast mass on physical examination in whom mammography fails to demonstrate an abnormality, a supplemental ultrasound helped to further characterise the lesion.[17]

Ultrasound, an extremely efficient tool for imaging with efficient assessment of women with palpable lesions in the breast and ought to be done in all women.

A breast ultrasound should be the most important means of imaging for women having palpable breast lumps aged less than 30 years or those pregnant and or lactating women. For women aged 40 years and older,

mammography and ultrasound correlation is recommended. Ultrasound or mammography can be done for women between 30 and 39 years of age. Not much use has been found for using MR mammography and various other advanced imaging modalities in the routine evaluation and of breast lesions that are palpable.[18]

BREAST ANATOMY

DEVELOPMENT:

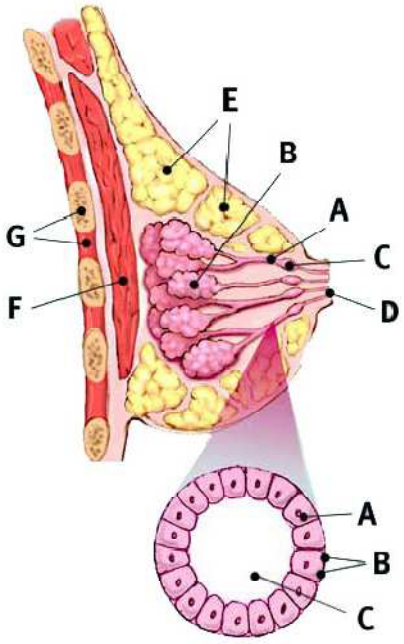
The breast is a tubuloacinar type of modified skin gland that develops from the mammary ridge in the embryo. A primitive embryonic ectodermal milk line runs from the base of forelimb to the region of hind limb. During 5th – 7th wk of intrauterine fetal development, the thoracic section will specialize and thicken to form the mammary ridge. The central part of the upper third of the mammary ridge persists to form the breast bud on the chest wall and in time the tail of Spence which extends into the axilla. At term a number solid outbuddings form a branching system of ducts, representing the future lobes of the breast. The ducts open onto a surface pit, which undergoes mesenchymal proliferation and gets everted to become the nipple.[19- 22]

TOPOGRAPHIC ANATOMY:

The breasts lie entirely within the superficial fascia of the chest wall. The retromammary space, separates the superficial and the deep fascia. It extends from the second rib (superiorly) upto the sixth or seventh costal cartilage (inferiorly) and from the sternal edge (medially)and the mid axillary

line (laterally). The breast is divided into a quadrant which is extending peripherally from the nipple. The maximum amount of fibro-glandular tissue is within the upper quadrant which also gives rise to the axillary tail of Spence which passes supero-lateral to the axilla. Lateral aspect of the breast overlies the Serratus Anterior and External Oblique muscles while the medial two thirds of the breast overlie the Pectoralis Major muscle. Suspensory ligaments of Cooper are fibrous strands or extensions of the superficial fascia that pass through the breast towards the skin and nipple. The Areola (a circular zone of pigmented skin)surrounds the nipple. The areola contains abundant specialized sebaceous glands know as Montgomery's tubercles. The secretion of these glands protects the nipple during suckling.

Fig. 1 Anatomy of Breast



	Breast profile:
A	ducts
B	lobules
C	dilated section of duct
D	nipple
E	fat
F	pectoralis major muscle
G	chest wall/rib cage

	Enlargement:
A	normal duct cells
B	basement membrane
C	lumen (center of duct)

Couple of possible explanations are there for why the breast has a tendency to develop carcinoma. The development of premalignant lesions such as atypical ductal hyperplasia is more likely seen in an 'elevated growth' environment.

To stimulate the growth of latent tumour cells, estrogen production is required within the breast which is caused by a naturally overactive aromatase.

BLOOD SUPPLY:

Arterial supply: The upper outer quadrant of the breast is supplied by the lateral thoracic artery which branches from Axillary artery. The central and medial portions of the breast are supplied by perforating branches of Internal Mammary artery. The branches of intercostal arteries with some branches from subscapular and thoracodorsal arteries supply to the lateral breast tissues.

Venous drainage: Drainage via Internal Thoracic, Axillary, Subclavian and the Azygos veins.

Lymphatic drainage: Bulk of the lymph drains towards the axillary nodes, but some passes to the Inter- costal and the Internal Thoracic chains, with nodes arranged in groups. Axillary nodes are divided into three levels according to its relationship with the Pectoralis Minor muscle. Level-I nodes are infero-lateral, level-II nodes are deep and level III nodes are supero-medial to this muscle. Lymphatic drainage of breast is important as it plays a crucial role in spread and staging of breast malignancies.

CHANGES IN SIZE & APPEARANCE OF BREAST TISSUE OVER TIME

Changes during Puberty: Puberty usually begins at 10 to 11 yrs of life among girls. The breast retains its rudimentary glandular structure until puberty, when the female gland enlarges under the influence of various hormones. The lacticiferous ducts proliferate forming ductules, acinar ducts and simple acini.

In a mature female breast, some 15-20 lobes drain by lactiferous ducts onto the nipple. The lobes are further subdivided into lobules which are surrounded by a fibrous and fatty interlobular stroma. A lobule are a group of acini which is supplied by one terminal duct and supported by a loose connective tissue, and is termed as Terminal Duct Lobular Unit (TDLU)

Changes during Pregnancy: Marked epithelial proliferation occurs within the TDLU with relative decrease in the surrounding fat and connective tissue. Prolactin, Insulin and Growth hormone stimulates the ductules to form secretary acini.

Changes after Menopause: After a woman reaches menopause (usually in her late 40s or early 50s), the body stops production of estrogen and progesterone. In this time, the breasts undergoes changes. For some, breasts become more tender and lumpy, occasionally forming cysts, while in others the breasts glandular tissue is replaced with fatty tissue as it shrinks after menopause. The breast has a tendency to increase in size and sag because the fibrous tissue loses its strength. After menopause the breast becomes less

dense and it is easier to detect breast cancer in older woman's mammogram films because the abnormalities are not hidden by breast density.

BREAST IMAGING MODALITIES

MAMMOGRAPHY: Mammography is the single most essential method in diagnosing breast diseases. Its areas of application consist of:

(i) **Screening:** mammography, the only imaging method to date that is suitable for screening.

(ii) **Problem solving / Diagnostic**: Apart from a small number of exceptions mammography is indicated as a diagnostic method in symptomatic patients. This not merely helps physicians in determining whether a lesion is potentially malignant or benign but it also screens for occult disease in the surrounding tissue.

CONVENTIONAL MAMMOGRAPHY

Mammography is high-resolution x-ray imaging of the compressed breast. This involves radiation transmission through the tissue and the projection of anatomical structures on a film screen or image sensor.

i. Two imaging projections of each breast, craniocaudal (CC) and mediolateral oblique (MLO - 45^0) views are obtained usually by mammography.

ii. Additional views may be required to visualize breast tissue more effectively.

iii. Evaluation of the augmented breast, be it screening or a diagnostic examination, should include, when possible, the routine CC and MLO views as well as magnification views.

iv. The interpreting physician does not need to be present at the facility to monitor the examination when the patient is imaged.[10]

Misperceptions regarding the risk of radiation from mammography persist despite the fact that no woman has ever been shown to have developed breast cancer as a result of mammography, not even from multiple examinations over many years time at doses much higher than the current dose of 3 to 4 mGy (0.3– 0.40 rad) per two-view per breast examination. The main risks and other adverse consequences from screening include pain and discomfort from breast compression, patient recall for additional imaging, and false-positive biopsies. Although these risks affect a larger number of women than those who benefit from screening, the risks are less consequential than the life-sparing benefits from early detection.[23]

The sensitivity of mammography mainly depends on the composition and density of the breast parenchymal tissue. Denser the breast tissue, harder it is to look for small lesions, even though tiny foci of calcification can be seen. Initially, mammogram has to be used to detect any mass or calcifications followed by architectural distortion and any skin changes.

A *mass* by definition is a space occupying lesion imaged in two different views in mammography. It is furthermore categorized by its shape, margins, density, size, orientation and calcifications. *Density* is defined as a collection seen in only one mammographic view.

Shape: Irregularity shape of a mass should be a worrisome feature as it hints at a lesion with indistinct margins. Certain lesions involving the skin such as warts and seborrhoeic keratoses have a radiolucent / air halo which is classically seen due to its variegated surfaces.

Margin analysis: signifies the zone of transition of a mass from the normal surrounding breast parenchyma. When a mass has ill-defined, microlobulated or spiculated margins it is crucial to identify it and document it as there are high chances of it being a malignancy.

A sharply marginated or a well circumscribed mass, with or without a radiolucent halo, is more likely to be benign.

Circumscribed masses with irregular or microlobulated margins are more likely and considered suspicious for malignancy with magnification views obtained and histopathological correlation should be suggested.

Masses with spiculated margins are indicative of being malignant unless proven otherwise. Radial scar or sclerosing adenosis can be other possibilities for spiculated margins. Post operative scar can be another possibility for a spiculated lesion.

Density describes the relative attenuation of a lesion in the breast compared to the normal fibroglandular tissue. Mammographic breast density itself is an independent risk factor for developing breast carcinoma, with estimates of relative lifetime risk ranging from 2.8 to 6.0 and risk increases in proportion with percentage breast density as the sensitivity of mammography declines. Radiolucent masses / fat containing are most likely to be lipoma, hamartoma, oil cysts, galactocele or fibrolipoma that are most likely benign, except for suspicious characteristics.[24,25]

Calcifications can be associated with various lesion in the breast. There are specific characteristics that are seen in typically benign type of calcification and in malignancy.

Micro calcifications are seen as bright dot-spots on screening mammograms, usually in the form of clusters. These are calcium deposits from cell secretion and necrotic cellular debris. The shape and the distribution of breast calcifications indicate malignancy. Benign micro calcifications are usually smooth and sharply outlined and have high uniform density. Malignant micro calcifications generally appear in irregular shape and is variably distributed.[19, 26,27]

In the official BI-RADS publication, the calcifications have been described by its appearance and distribution in the breast parenchyma. Accordingly the appearance of typically benign calcifications that are described below:[28]

1. **Rim-like or eggshell calcifications:** calcifications are thin, round, rim-like. It is commonly seen in fat necrosis or in the walls of cysts.
2. **Popcorn-like and coarse calcifications**: Degenerating fibroadenomas also known as involuting fibroadenomas show classically these type of calcifications within.
3. **Vascular calcifications:** Also known as calcification of arteries are described as railroad track type of calcifications and shows a linear configuration (either singly or in parallel pairs). It should be differentiated from calcifications that are malignant when the calcifications are small or single and linear.
4. **Large, rod-like calcifications or secretory deposits:** Thick calcific foci seen following the duct towards the nipple and are due to secretory disease.
5. **Milk of calcium:** Viewed on imaging as tiny, teacup-shaped calcifications that are within small cysts which is visible on the lateral view. Occasionally, the soft-tissue shadow of the cyst which is small and rounded can also be appreciated.
6. **Lucent-centered calcifications:** These are rounded calcifications with a lucent center usually representing dermal calcifications. Larger calcifications with lucent centers may be due to oil cysts or fat necrosis and may also follow surgery or trauma.

Calcifications that are of intermediate concern

Amorphous calcifications: These are very tiny, hazy calcifications and are often difficult to pick up on CR machines. These could be benign or malignant.

Calcifications that are proven to be highly suspicious for malignancy

Fine, linear or branching calcifications: These are linear, rod-like calcifications which are classically seen in malignancy.

Pleomorphic calcifications: micro calcifications of various sizes and shapes that are distributed in clusters.

According to distribution, calcifications are classified as below :-

Clustered or grouped: These can be seen in both benign and malignant conditions and are described as calcifications (five or more than five in number) seen in 1 cm^3 of area. A loose cluster ($<10/cm^2$), is more probable to be benign, while a compact cluster ($>20/cm^2$) has a higher probability to be due to a malignant cause.[29]

Linear, segmental: Calcifications arranged in a line and showing a branching pattern which is suggestive of deposits within a duct. Most commonly malignant lesions involving the duct begin at the terminal ducts and the calcifications are distributed in a linear manner.

Regional: Calcifications are seen in a large volume, not necessarily conforming to a duct; more likely to be benign.

Diffuse or scattered: These calcifications are seen all over the breast and may be bilateral. They are almost always benign. The pattern of calcifications in the breast can point towards a lesion having a tendency of being more malignant. Liberman et al.[30] conducted a study and found that 74% of calcifications that were distributed segmentally were proven to be malignant, whereas those having linear distribution of calcification proved 68% to be malignant followed by 36% malignancy of lesions with clustered based calcifications.[31,32] Pleomorphic type of calcification when seen within a mass are usually proved to be a typical of invasive ductal carcinoma on histopathology. Usually in cases with isolated clustered calcifications, invasive components will be 5 mm or smaller.[33] DCIS has a typical appearance of no obvious mass with just calcifications within the breast parenchyma: This appearance was seen in two separate studies where 37 of 54 DCIS lesions in one series[34] and in another study 72 of 100 women showed similar characteristics.[35]

To conclude, with the help of morphology and distribution of calcification a breast lesion can be categorized into benign, of intermediate-concern, and malignant types. A more appropriate way of classifying calcifications in relation to the breast lesion would be to categorize them according to BI-RADS.[36] The definitely benign type of calcifications can be categorized as BI-RADS 2. Calcifications of intermediate concern should be closely monitored and can be categorized into BI-RADS 3. Pleomorphic and casting-type calcifications are categorized as BI-RADS 4/5 and a FNAC / biopsy is recommended.[37]

FULL FIELD DIGITAL MAMMOGRAPHY

In digital mammography, the processes of image acquisition, display and storage are separated, which allows optimization of each. Radiation which is transmitted through the breast, is absorbed by an electronic detector. Once the information is recorded, it can be displayed by using computer image-processing techniques to allow the arbitrary settings of image brightness and contrast, without need for further exposure to the patient.[38]

The digital mammographic equipment has demonstrated superiority in detection of lesions with low contrast.[39,40] This has helped in especially with women having dense breasts which helps to augment the quality of diagnostic images. The main advantage of digitalising mammography is the ability to read the images on the console which gives an added advantage and enhances the rate of cancer detection especially in women with dense breasts by increasing the contrast resolution. There was not much difference in the rate of cancer detection in screening populations who had undergone mammography with conventional versus digital mammography in four large-scale trials.[41-45]

COMPUTER AIDED DETECTION

Multiple studies have made known that interobserver errors are seen commonly in breast cancer screening.[46] The radiologist misinterprets an abnormality or is not aware of the abnormality. An estimate of around 20-30% of the breast carcinoma's could be detected in earlier screening without an undesirable raise in the rate of recall.[47,48]

Due to the high number of normal cases, breast carcinoma screening is a difficult task (i.e. less than 1% of the screened women have breast cancer). To assist radiologists in detecting signs of cancer, a software developed to mark areas on mammograms that appear suspicious which may point towards the possibility of the patient having breast cancer. The final decision is made by the radiologist and these systems merely act as a second reader. The false positives (cases that are recalled unnecessarily) and false negatives (malignant cases that were not recalled) could be decreased with the help of CAD software.

A single view of the breast is used by CAD systems to analyse & detect micro calcifications and mass lesions. A two step procedure is used by CAD programs. Suspicious locations inside the breast region are detected firstly. In the next step, the image which was located in the specific areas in the breast are segmented into regions, and finally various characteristics are calculated for each region. Using these specific calculated characteristics of a lesion, CAD determine the true benignity and true malignancy and also helps eliminate false positivity.

Multiple views of the breast are taken by which the newer CAD systems are trying to incorporate information. It uses several projections of the breast and views obtained from successive screening rounds for assessing the tumour behaviour over time. A tumour can sometimes only be seen on a single view of image and this gives a better outcome. Using

various views which have been imaged at different times, the lesions in breast can be accessed on the rate of growth compared to each image taken as benign masses grow slowly whereas malignant lesions change considerably rapidly.

ULTRASOUND:

Similar to Mammography, USG has a vital part in imaging lesions in the breast. USG is valuable in evaluating palpable breast masses which are hidden on mammogram, to evaluate breast lesions in women younger than thirty years of age which is suspected on clinical examination and to further evaluate the various abnormalities demonstrated on the mammogram. USG is also helpful in the guidance of therapeutic procedures and biopsies, and more lately, research is underway to evaluate the role of USG in cancer screening.

Originally, USG was chiefly used as a efficient and cheap means to differentiate cystic from solid breast masses. There is no exposure of the patient to any form of ionizing radiation which is extremely vital especially in young or pregnant patients. Furthermore, women younger that 30years have glandular breast tissue which normally appears dense on mammogram, reducing the diagnostic sensitivity in this group. Evaluation of breast abscesses is better done with USG than mammography, which is another indication for breast USG.

Classification of benign, indeterminate, and malignant nodules

Technical improvements in ultrasound equipment, prospectively led to the classification of breast nodules into one of the three categories (i.e. benign, indeterminate or malignant).

To be classified as benign, a nodule has to have no malignant characteristics and it should also demonstrate 1 of the 3 following combinations of benign characteristics:[49]

a. Intense uniform hyperechogenicity.
b. Longitudinal more than anteroposterior diameter or ellipsoid (parallel) orientation along with a thin, echogenic peripheral capsule.
c. Few lobulations (≤ 3 in number) with a thin echogenic capsule.

To say a nodule is indeterminate by default, is if it has no malignant characteristics and none of the previously listed combinations of the three benign characteristics.

To be classified as malignant, the lesion requires to have any of the following characteristics:

a. Spiculated contour
b. Anteroposterior diameter more than longitudinal diameter
c. Angular margins
d. Marked hypoechogenicity
e. Posterior acoustic shadowing

f. Punctate calcifications (Amorphous)

g. Duct extension

h. Branch pattern or microlobulation

Fine needle aspiration cytology (FNAC) of the lesion was done under ultrasound guidance. The skin was disinfected with the disinfectant. The needle was inserted near one of the short sides of the transducer and it was advanced along a trajectory lying parallel to the long axis of the transducer. Until the lesion was penetrated by the needle, as it had advanced the needle was clearly visualized on the monitor. Aspiration was then applied and the tip was moved in various directions to collect multiple samples. While the needle was being withdrawn, no aspiration was applied.

The collected specimen was sent for histopathological examination which was done by the Pathologist. The material which was collected was used to prepare at least two slides: one for Papanicolaou staining (after fixation in 95% ethanol), and another air-dried for staining with May-Grunwald-Giemsa stain. After the slides were smeared with aspirated material, they were immediately sprayed with an appropriate fixative.[50]

USG guided procedures which can be done, such as percutaneous biopsy, cyst aspiration, abscess drainage in selected cases, needle localization of masses for surgical excision and therapeutic radiofrequency or cryoablation.

AUTOMATED BREAST ULTRASONOGRAPHY (ABUS)

ABUS aims to remedy the issues of handheld USG with operator dependence, image variability, and physician time for acquisition. All images are obtained by using standardized views by nonphysician personnel. The automated imaging process of ABUS is quicker to acquire and requires less training than a handheld USG. The standardized review process, allows quick navigation through breast and rapid review of many images.[51]

MAGNETIC RESONANCE IMAGING

MRI is being studied to determine its efficacy in diagnosing breast masses. Gadolinium contrast is to be used to enhance the vascularity of malignant lesions. MRI is highly sensitive (85% to 100%) but it lacks specificity (47% to 67%)[52,53].

MRI is inferior to mammography in detecting in situ cancers and for cancers smaller than 3 mm. There is no cost benefit over excisonal biopsy for verifying malignancy.

Research suggests two possible roles for MRI in diagnosis of breast mass:

1) To evaluate patients with silicone breast implants and

2) To assess patients where evaluation done by ultrasound and mammography was challenging.[54]

A recent study had compared the efficacy of mammography and MRI in women with a family history of breast cancer or a genetic susceptibility to the disease.[55]

The sensitivity of MRI was higher than that of mammography in detecting breast carcinoma and MRI also improved detection of early breast cancers in carriers of BRCA mutations. It had a lower specificity than mammography, which required additional evaluations.

Limitations of MRI include: high cost, lack of easy availability, patient corporation and the need for giving contrast material.

NUCLEAR MEDICINE:

Imaging method which involved the use of metabolites for visualising the functional / metabolic properties of a tumour.

SCINTIMAMMOGRAPHY:

Tumour specific diagnostic modality of breast which uses radiopharmaceuticals. After injecting a radiopharmaceutical, the breast is evaluated by single positron emission computed tomography (SPECT). Scintimammography might be used to suggest against performing a biopsy in the case of a lesion predictive to be benign, thereby bringing a reduction in the number of negative biopsies performed. On the other hand, if a lesion is predictive of being malignant where the mammogram taken was suggested to show benignity, subsequently it improves the sensitivity of screening.

PET:

Not so useful in estimating the biologic behaviour of a tumour, in determining extent of disease in the breast or in determining axillary lymph nodal status.

INTERVENTIONAL PROCEDURES

The best method of interventional procedure is used after the initial clinical and diagnostic modalities are completed.

GALACTOGRAPHY:

Galactography refers to the examination of lactiferous ducts using a contrast medium. Debris, ductal carcinoma in situ, fibrocystic changes or a papilloma can be the cause of filling defects visualised in the procedure. Indicated in women with unilateral nipple discharge emanating from one/two ducts and is not to be indicated in women having galactorrhoea or serous discharge from multiple ducts.

PRE OPERARTIVE NEEDLE LOCALIZATION:

The ever-increasing use of mammography has resulted in an increased rate of detection of clinically occult disease. Non-palpable lesions can be localized under mammographic/ultrasound guidance or less commonly, under CT / MRI guidance for subsequent excision. A visual clue such as a needle which is kept in close proximity to the lesion, to assist the surgeon.

PERCUTANEOUS BIOPSY:

The ability to perform biopsies percutaneously, rather than surgically has numerous advantages. Considerable cost reduction and reduction of operating room time is also seen. Due to smaller volume of tissue removed, the morbidity is decreased, no cosmetically deforming scarring occurs hence no architectural distortion is seen on follow up mammograms.

Percutaneous biopsy can be performed with a variety of biopsy techniques. Fine needle aspiration cytology has variable sensitivity data of 53-100%.A negative cytological finding may generally not be used to avoid surgical biopsy. Core needle biopsy has now become a well established technique under mammographic, sonographic or stereotactic guidance. Core needle biopsy is the standard method for the work up of masses, probably benign lesions or for proving malignancy in suspicious lesions. It permits histological diagnosis as it has cores of tissue. The sensitivity ranges between 92%-98% with a specificity of 100%.

VACUUM ASSISTED NON SURGICAL BREAST BIOPSY:

The most accurate biopsy technique for the work up of microcalcifications is vacuum biopsy. The major limitation is the high cost of these biopsy probes.

BREAST DISORDERS

DEVELOPMENTAL ANAMOLIES:

The most common congenital abnormality of the breast is ectopic breast which is also known as mammary heterotopia. It has been described as both aberrant and supernumerary breast tissue which is mainly seen along milk line. Nonetheless, if an ectopic breast tissue is found in a location outside the milk line it should be thought of as various studies have documented breast tissue being found in unusual sites such as knee, lateral thigh, buttock, face, ear and neck. [56]

Most common location of aberrant breast tissue is usually the axilla. If there is a breast tissue in an abnormal location there are more chance for a malignancy to develop at an earlier age which is considered very rare.[57-59]

BENIGN TUMOURS

FIBROADENOMA:

Fibroadenoma, a common benign tumour of the breast and represents a group of hyperplasic lobules of breast called "aberrations of normal development and involution" (ANDI) which are seen commonly in young women[60-62].

Giant fibroadenomas are lesions that are ≥ 8 cms. On mammogram, the classic fibroadenoma is an oval or lobular mass with equal density and smooth margins. As the fibroadenoma ages, it become sclerotic, less cellular and popcorn like calcifications are seen at the periphery. Subsequently, the

entire lesion may be replaced by dense calcification, which is an involuting fibroadenoma. On ultrasound imaging fibroadenomas are well circumscribed, oval, homogenous masses, which are usually wider than tall with upto three gentle lobulations.

Fibroadenomas include ductal elements, which can undergo malignant transformation and ductal or lobular carcinoma in situ have been reported. Any suspicious change such as an enlarging lesion or atypical findings on ultrasound or a lesion above 2.5 cm should prompt for pathological diagnosis.

PHYLLODES TUMOUR:

Previously called cystosarcoma phyllodes, is a benign tumour arising in women in their 5th decade and can be quite large. A phyllodes tumour contains both epithelial and stromal elements. Phyllodes tumours have around 10% chances of undergoing malignant change which can metastasize to lung. The characteristics of phyllodes tumour on mammography are a dense, round or oval, lobulated, non calcified mass with smooth borders. Ultrasound shows a smoothly marginated, inhomogenous mass which seldom contains cystic spaces producing acoustic posterior enhancement and it can be mistaken for a circumscribed cancer or fibroadenoma.

FIBROCYSTIC DISEASE:

Fibrocystic changes (FCCs) comprises one of the most frequently observed benign breast disorder. It is generally seen in premenopausal women

aged between 30 and 50 years.[63-69]On mammogram tea-cup, low-density round calcifications can be seen involving multiple lobes. FCCs could be multifocal and bilateral. Females commonly present with pain in the breast and tender nodularities within. Over the years, the disease has been reported to undergo malignant changes in females, though its very rare.[70]

CYSTS:

Cysts are round, fluid-filled lesions which are found commonly in females from 35-50 years of age in almost 33% of women. Mammography or clinical breast examination cannot differentiate a cyst from solid mass. Ultrasonography is crucial to distinguish a solid from a cystic lesion which can be confirmed on fine needle aspiration cytology. A complex cyst is diagnosed on ultrasonography which has features such as thin septations or internal echoes, thickened and or irregular wall in addition to an absent posterior echo enhancement.[71]

The malignancy rate for a complex cyst, which is 0.3% as described by Venta et al., is lower than that for lesions classified as "probably benign." Management in these patients can be to do follow-up imaging studies [72].

However, if the lesion moreover includes an intracystic mass (intracystic nodule), it should be regarded as "suspicious for neoplasm" and must be managed as a solid lesion. Either a surgical biopsy or a core needle biopsy is indicated for these lesions [73].

ADENOSIS:

Adenosis is a proliferative lesion of the breast mostly involving the lobular units and is characterized by an increased size or number of glandular components. Sclerosing and microglandular adenosis are of importance from the numerous types of adenosis described.

A palpable breast mass or a suspicious finding at mammography can give a clue to an underlying sclerosing adenosis. A patient having either invasive or in situ carcinoma can have a co-existing sclerosing adenosis. It has been found that one of the risk factors for invasive breast carcinoma can be sclerosing adenosis.[74]

Microglandular adenosis of the breast is characterized by proliferation of round, small glands which are distributed irregularly within dense fibrous and or adipose tissue. Although microglandular adenosis is considered benign, there is some evidence pointing towards its potential of this lesion to become invasive carcinoma. Microglandular adenosis also has a tendency to recur if not completely excised.

PAPILLOMA:

Papillomas can be either solitary or multiple and is the most common intraductal breast lesion. Solitary papillomas are central or peripheral, that originate in the ductal epithelium and are often seen in the subareolar region (within 1cm of the nipple).

Tumours starting within the terminal ducts, further from the nipple are called peripheral papillomas and are considered a risk factor for breast cancer.

Often papillomas are not seen on mammography or ultrasound at all. When seen on ultrasound, papillomas are solid, round / oval or microlobulated hypoechoic masses. Galactography reveals intraductal filling defect, duct ectasia or obstruction.

Ultrasound reveals an intraductal mass lesion seen within the duct with a vascular stalk visible on colour doppler studies. Women having breast papilloma have increased chances of developing invasive breast carcinoma.

LACTATING ADENOMAS:

These occur in young patients in their late trimester or in the post partum period. They are solid, well circumscribed masses and is found to be enlarging rapidly during pregnancy. On ultrasound, a lactating adenoma is lobular or oval and is smoothly marginated which contains cystic or necrotic spaces.

RADIAL SCAR:

It is a benign proliferative breast lesion that is not related with post-biopsy scar. Radial scars and its larger variants called complex sclerosing lesions, may include adenosis and hyperplasia. A radial scar has a central portion that undergoes atrophy, thus resulting in a scar-like formation, pulling in of the surrounding glandular tissue and producing a spiculated mass. On

mammography, it appears as a spiculated mass with either white or dark central area and on ultrasound it appears as a hypoechoic mass, with or without posterior acoustic shadowing.

HAMARTOMA:

Hamartoma is an uncommon benign tumour-like nodule of the breast and is also known as lipofibroadenoma or fibroadenolipoma or adenolipoma. It is composed of varying amounts of glandular, adipose and fibrous tissue. Clinically, hamartoma presents as a discrete, encapsulated, painless mass. The characteristic mammographic appearance is a well circumscribed area consisting of both soft tissue and lipomatous elements, surrounded by a thin radiolucent zone.[75,76]

LIPOMA:

A benign tumour of breast which is usually a solitary tumour made up of mature fat cells. It is seldom a complicated process to differentiate a lipoma from other breast conditions clinically, thereby getting a radiologists opinion for imaging.[33] The clinician on palpation finds a well-circumscribed, lobulated or smooth margin mass which is soft and non-tender. FNAC reveals multiple fat cells which could also show epithelial cells within. Combination of both sonomammography usually delivers negative results in small tumours and can identify lesions which are large. After a diagnosis of lipoma on FNAC or core needle biopsy and no imaging features of any suspicious lesion on ultrasonography and mammogram, the patient can be

followed up clinically by palpation after 6 months. If the diagnosis is not confirmed or the mass has grown rapidly, it should be completely removed.[77,78]

LYMPH NODE:

Intramammary lymph nodes are not uncommon and seen often located in the upper quadrant of the breast. To make a diagnosis of an intramammary lymph node the fatty hilum should be visible within.

Normal intramammary lymph nodes have a diameter of less than 1 cm. A non-pathological lymph node in the axilla that is enlarged is size will depend on the size of fatty hilum.

GALACTOCOELE:

An obstructed milk duct usually leads to galactocoeles that can occur at a short interval after breast feeding is stopped or during lactation. On mammography, galactocoeles are viewed as an intermediate lesion, unless an obvious fat-fluid level is visualised. Even if the radiologist is not being able to see the fat-fluid level within the lesion and if fat can be demonstrated within the mass it can still be benign. On ultrasound, a complex lesion may be seen which can be cystic, mixed cystic & solid or solid.

FAT NECROSIS*:*

Fat necrosis occurs with history of previous trauma, usually surgery or blunt trauma and is due to saponification of fat. On mammography, fat necrosis typically contains a fatty lipid centre and it is round in shape.

INFLAMMATORY AND RELATED CONDITIONS :

MASTITIS

A mixture of inflammatory and reactive changes can be seen occurring in the breast. Inflammatory breast cancer, can be a great mimicker for an infectious or an inflammatory cause. An initially misdiagnosed lesion, mastitis can even develop without a pre-existing lesion. Sonomammographic combined imaging modality is essential in diagnosing mastitis as a non-invasive method which can be confirmed on FNAC / biopsy.

ACUTE MASTITIS:

Acute mastitis, also known as puerperal or lactation mastitis, usually occurs during the first three months postpartum which occurs as a result of breast feeding. Abscess formation and septicaemia can be the end result of acute mastitis if not treated. Diagnosis is made on patients clinical features and signs of inflammation in the breast. On ultrasonography a non-invasive method of diagnosis can be achieved, thereby avoiding unnecessary need for FNAC and treating with antibiotics [79].

GRANULOMATOUS MASTITIS:

Granulomatous mastitis occurs as an effect of a foreign material, by an infectious etiology or an autoimmune systemic disease (Sarcoidosis / Wegner's granulomatosis) which affects the breast. Immunologic and microbiologic testing is required to identify the accurate etiology followed by

histopathologic evaluation of the lesion. Various organisms can be the cause of granulomatous mastitis .[80,81]

A very rare entity of a granulomatous mastitis can be due to tuberculosis. Nonetheless, both clinical and radiological features of tuberculous mastitis can be easily confused with either breast carcinoma or pyogenic breast abscess and it cannot be diagnosed clinically. Final diagnosis is given by the identification of typical histological features and mycobacterial culture of the disease.

MAMMARY DUCT ECTASIA:

It is also called as periductal mastitis which is a unique entity that can mimic clinically, an invasive carcinoma. A disease which is mainly seen in parous women with ages ranging from middle-aged to elderly and can have various clinical presentations such as complaints of nipple discharge, noncyclical mastalgia, a subareolar mass and / or nipple retraction or inversion. An asymptomatic lesion which is usually detected by presence of microcalcification detected on mammography.

BREAST CANCER:

Breast cancer represents one in four of all the cancers occurring in women which is the most frequently diagnosed cancer among women in 140 countries worldwide and is now one of the leading causes of cancer related deaths among women. [1,2]

IN SITU CANCER

In situ or non-invasive carcinoma is when the malignant cells are completely contained in the ducts or lobule and hasn't breeched the basal membrane. The rest of the breast tissue is spared and there is no distant spread of cancer. It can further progress into a more serious type of invasive carcinoma of breast. The two types of non-invasive breast carcinoma: lobular carcinoma in situ (LCIS) and ductal carcinoma in situ (DCIS).

Characteristic appearance of DCIS on mammogram is presence of micro calcifications. LCIS usually is much more difficult to detect on mammography and is usually discovered incidentally when a biopsy is being taken for another abnormality.

INVASIVE CANCER

Carcinoma is invasive when it breeches the basement membrane and infiltrates into the surrounding tissue. Depending on the stage of the tumour at the time of detection, the appropriate treatment is planned accordingly. Two main features which are crucial to stage a tumour are its size and whether distant metastasis has occurred.CC breast of invasive type can have size ranging from 10mm - 80mm in largest diameter. Smaller than 20mm, a size of a lesion with no distant metastasis, there are better chances for successful treatment. Hence it is crucial to detect breast carcinoma at a very early stage.

On mammogram, it is extremely crucial to detect micro calcification and focal masses. Features that favour a mass to be malignant are spiculated margins. A benign mass tends to have sharp and well-defined borders whereas a lesion with jagged or spiculated border are malignant.

A halo or capsule surrounding a radiolucent lesion is more often than not benign. High radio opaque mass should be looked at with a high degree of turning malignant where it is having an irregular or ill-defined boundary.

Micro calcifications appear as bright dot-spots on screening mammograms, usually in the form of clusters. These are calcium deposits from cell secretion and necrotic cellular debris. Breast calcification can indicate malignancy depending on the shape and distribution of the calcifications. Benign micro calcifications are often smooth, sharply outlined and have a high uniform density. Malignant micro calcifications usually appear in irregular shape and are variably distributed.[82-84]

PAGETS DISEASE:

A benign appearing eczematoid lesion of the nipple caused by large malignant cells (paget's cells) arising from the ducts and invading the surrounding nipple epithelium.

Mammographic findings seen calcifications in 72%, soft tissue abnormality with calcifications in 12% and only soft tissue abnormality in around 10% of patients.

BREAST IMPLANTS:

Indications for a breast implant can consist of a women not being satisfied with the size of the breast, or with increasing flattening of the breast after pregnancy or with increasing age. Seldom, women have congenital absence or underdevelopment of one breast who may request unilateral, rather than bilateral surgery, to rectify the asymmetry.

Patients who have undergone postoperative mastectomy undergo reconstruction breast surgery in the recent times. It involves by placing an implant within (out of the many varieties available at large) or also can be by modeling of autologous myocutaneous flaps. For a Radiologist, knowing the normal appearance of the various implants used is crucial and to know its appearance on the different imaging modalities to identify the pathologies.[85]

Materials & Methods

MATERIALS AND METHODS

STUDY DESIGN

Cross-sectional study.

STUDY PERIOD

12 months (June 2015 – June 2016)

STUDY SETTING

Department of Radiodiagnosis and Department of Pathology, Sree Mookambika Institute of Medical Science, Kulasekharam, Kanyakumari (District), Tamil Nadu.

STUDY POPULATION

Females more than 30 years of age with breast lesions and having BI-RADS 2 and above on imaging.

INCLUSION CRITERIA

- Females more than 30 years coming for routine breast screening, found to have BI-RADS 2 and above.
- Females more than 30 years associated with or without lump or nodularity in the breast.
- Females more than 30 years with complaints of pain in the breast referred to Department of Radiodiagnosis.
- Females with history of nipple discharge.

EXCLUSION CRITERIA

- Pregnant women
- Bleeding disorders
- Patients with known history of breast malignancy (BI-RADS 6).

SAMPLE SIZE

Sample size was calculated using the formula

Sample size (n) = 4pq/d2,

Where, p = Prevalence

q = 1 – Prevalence

d = Precision is 20%

Substituting in the sample size formula,

= 4 x 60 x 40 / 122

= 9600 / 144 = 66.

Total 66 patients were included in the study.

EQUIPMENTS / INSTRUMENTS

Conventional mammography (Mammography System. MAMMOMAT 3000 Nova Siemens, Siemens Medical Solutions USA, Inc), Ultrasongraphy (Siemens Accuson 300 & Siemens Accuson X600, Siemens Medical Solutions USA, Inc), disposable needles (21-27 gauge) (Hindustan syringes & Medical devices Ltd), Spirit (Hy-Chem laboratories), fixative (95% ethanol).

The study was approved by Institutional Research Committee and Institutional Human Ethical Committee.

SELECTION OF PATIENTS

The women who fulfilled the inclusion criteria, exclusion criteria and with valid consent were included in the study.

All patients were subjected to conventional mammography, ultrasonography and FNAC under USG guidance.

CONVENTIONAL MAMMOGRAPHY

Mammography is a high-resolution X-ray imaging of the breast obtained by compression of the breast tissue. X-rays are transmitted through the tissue and the anatomical structures are projected onto a film screen or image sensor. Two imaging projections of each breast, craniocaudal (CC) and mediolateral oblique (MLO) views are routinely obtained by mammography.[10]

ULTRASONOGRAPHY

Using Siemens Accuson ultrasound machines, the USG was done with the patient lying in supine position. The high frequency linear probe (Transducer VF 10-5) had been used to image the breast tissues clearly. Both the breasts were exposed and the transducer was swept in radial and anti-radial direction to look for any abnormality.[86]

FNAC

Fine needle aspiration cytology (FNAC) of the lesion was done under ultrasound guidance. The skin was disinfected with the disinfectant. The needle was inserted near one of the short sides of the transducer and it

was advanced along a trajectory lying parallel to the long axis of the transducer. Until the lesion was penetrated, the needle was continuously visualized on the monitor as it advanced towards the lesion. Aspiration was then applied and the tip was moved in various directions to collect multiple samples. While the needle was being withdrawn, no aspiration was applied. The collected specimen was sent for histopathological examination which was done by the Pathologist.[50]

DATA ANALYSIS

- Data was collected and entered into MS Excel 2007.
- Software(s) which were used for the statistical analysis: Data was analysed by Statistical Package for Social and Sciences (SPSS version 16.0).
- Statistical tests which were used for data analysis: descriptive statistics, Chi square test, sensitivity and specificity with correlation.
- Significance level was decided before starting of study: 0.05 ($P<0.05$) at 95% confidence interval.

Analysis & Interpretation

RESULTS

GENERAL INFORMATION

The study group comprised of a total number of 66 patients who had come to the Department of Radiodiagnosis for the evaluation of their breast lesions. There is no missing data from any of the subjects.

BASELINE CHARACTERISTICS

The age distribution of the study group varies from 30 to 66 years. The maximum number of patients with breast lesion belonged to the age group of 30 to 40 years (Fig. 2). 20% of the study population had a family history of breast cancer, while the rest of them had no relative who had suffered from breast cancer (Table 3). 28 out of 66 patients who had undergone mammography & ultrasonography had mainly come for complaints of lump in the breast followed by 16 who were evaluated for pain in the breast. Most of the patients who had come for screening mammogram had a positive family history of breast cancer (Table 4).

CHARACTERISTICS OF BREAST LESIONS ON MAMMOGRAPHY

Out of the 66 patients, 33% had fibro-fatty breast tissue (Table 5). 29 of the total breast lesions were in found in the upper outer quadrant (Table 6). There was an equal distribution of round and oval shaped lesions on mammography (Table 7). 44 of the 66 lesions had well defined margins while 9 of them were indistinct, 8 microlobulated and the rest (5) had spiculated

margins (Table 8). Only a single lesion was fat containing, while 2 of the lesions had low density and the remaining 63 lesions had high density on mammogram (Table 9). 84% of breast lesions had no calcifications seen on mammography (Table 10). The overlying skin was normal in 61 of the patients while 3 of them had skin retraction and 2 of them had skin thickening on mammography (Table 11). Only 4 of the patients with lesions had nipple retraction on mammography (Table 12).

On mammography, 45% of the patients had benign lesions (BI-RADS 2) in the breast, while it was 13.6% of the lesions were highly suspicious for malignancy (BI-RADS 5) (Table 13).

CHARACTERISTICS OF BREAST LESIONS ON ULTRASONOGRAPHY

Oval shaped lesions at 51.5% were more than round lesions at 48.5% when visualised in ultrasonography (Table 14). As shown in Table 15, the most common type of margin of lesion on ultrasonography was well circumscribed (54.5%) and the least common was spiculated margins (9%).
38 of the lesions were hypoechoic on ultrasound followed by 21 anechoic lesions, 5 complex cystic lesions and lastly followed by a single hyperechoic lesion and a single isoechoic lesion (Table 16).

32 of the lesions showed no posterior echo intensity on ultrasonography as described in Table 17. Most lesions (57.6%) showed a

normal longitudinal versus anteroposterior diameter ratio (Table 18). 89.4% showed no skin retraction while 9.1% of the lesions showed skin retraction and a single lesion had thickening of the overlying skin on USG (Table 19). There was no infiltration of muscle and chest wall structures in 64 of the cases whereas infiltration was seen in 2 of the cases (Table 20).

Ultrasonography showed 57.6% of patients had benign lesions (BI-RADS 2) in the breast while 12.1% had lesions highly suspicious for malignancy (BI-RADS 5). (Table 21)

COMPARISON OF MAMMOGRAPHIC & ULTRASONOGRAPHIC FINDINGS WITH FNAC

FNAC showed that out of the total 66 lesions, 50 of them were benign and 16 were positive for malignant cells (Table 22).

The positive predictive value (PPV) of mammography was 76% and the negative predictive value (NPV) was 24% for benign lesions while the PPV was 61.5% and the NPV was found to be 38.4% for malignant lesions (Table 23).

The positive predictive value of ultrasonography was 97.1% and the negative predictive value was 2.9% for both benign and malignant lesions as shown in Table 24.

Combining both the modalities had a sensitivity of 94.2% for benign lesions and 96.4% for malignant lesions. The specificity after

combining both modalities was 97.1% for benign lesions and 92.2% for malignant lesions. (Table 25)

Most number of patients with benign breast lesions were in the age group of 30-40 years. The highest percentage of patients with lesions positive for malignancy was in the age group ranging from 41-50 years which accounted for 37.5% (Table 26, Fig. 3). All fat containing and low density lesions on mammography were benign on FNAC and the lesions which were of high density turned out to be either benign or malignant (Table 27, Fig. 4).

Out of the total 16 FNAC proven malignant cases, the most common site was the central (retroareolar) region (5 cases). Commonest site was upper outer quadrant for benign lesions (Table 28, Fig. 5). All the oval lesions on mammography were benign except for one. Out of the 18 round lesions, 15 were found to be malignant (Table 29, Fig. 6).

All lesions with spiculated margins and with fine pleomorphic type of calcification in mammography were found to be positive for malignancy in both mammography and on FNAC (Table 30 & 31, Fig. 7 & 8).

All the oval shaped lesions on USG were proved to be benign on FNAC (Table 32, Fig. 9). All spiculated margin lesions in ultrasonography were found to be positive for malignancy on FNAC, while all the well circumscribed lesions were found to be benign (Table 33, Fig. 10).

All the 24 patients with benign lesion on FNAC had an anechoic appearance on USG, while all the malignant lesions were either hypoechoic (87.50%) or complex cystic lesions (12.50%) (Table 34, Fig. 11).

All the 35 lesions which had a longitudinal versus anteroposterior diameter ratio of more than one were benign on FNAC. Those not fulfilling the criteria turned out to be either benign or malignant in almost equal numbers - 15 & 16 respectively (Table 35, Fig. 12).

Fig.2: Age distribution of breast lesions

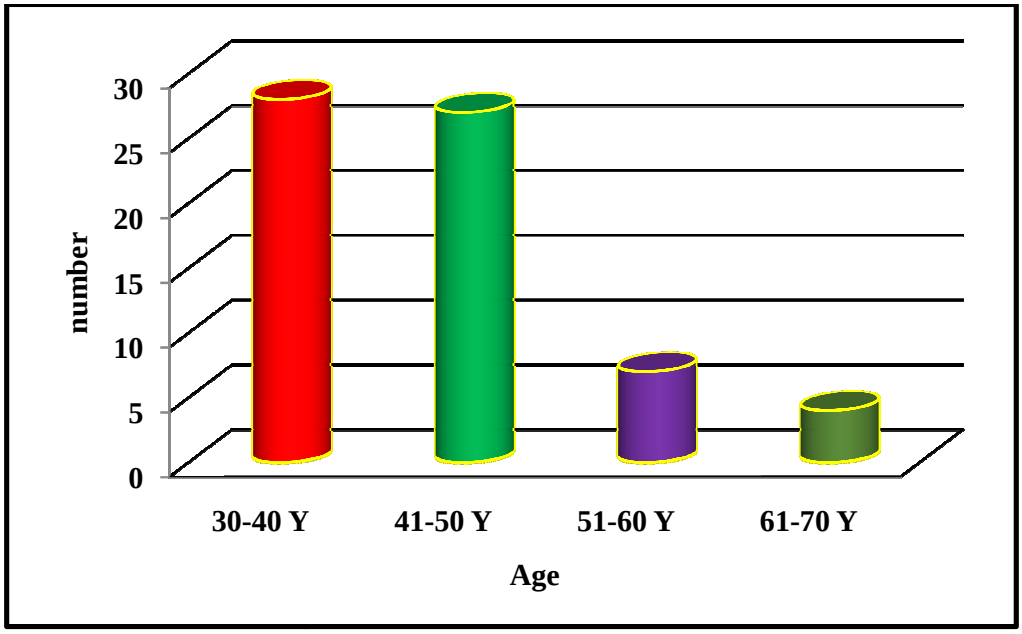


Table-3: Distribution based on family history of breast cancer

Family history of breast cancer	Number	Percentage (%)
Yes	13	19.70
No	53	80.30

Table-4: Distribution of patients based on indication of mammogram

Indication of mammogram	Number	Percentage (%)
Screening	13	19.70
Pain	16	24.24
Lump	28	42.42
Nipple discharge	9	13.64

MAMMOGRAPHIC CHARACTERISTICS

Table-5: Distribution of patients based on class of breast density

Class of breast density	Number	Percentage (%)
Predominantly fatty	16	24.25
Fibro-fatty	33	50.00
Heterogeneously dense	16	24.25
Extremely dense	1	01.50

Table-6: Distribution of patients based on location of lesion

Location	Number	Percentage (%)
Upper outer quadrant	29	43.94
Upper inner quadrant	09	13.64
Lower inner quadrant	08	12.12
Lower outer quadrant	05	07.57
Central (Retroareolar)	15	22.73

Table-7: Distribution of patients based on shape of lesion

Shape of lesion	Number	Percentage (%)
Oval	33	50.00
Round	33	50.00

Table-8: Distribution of patients based on margin of lesion

Margin of lesion	Number	Percentage (%)
Well defined	44	66.67
Microlobulated	08	12.12
Indistinct	09	13.63
Spiculated	05	07.58

Table-9: Distribution of patients based on density of lesion

Density	Number	Percentage (%)
High density	63	95.46
Low density	2	03.03
Fat containing	1	01.51

Table-10: Distribution of patients based on calcification of lesion

Calcification	Number	Percentage (%)
None	56	84.84
Coarse	01	01.53
Fine pleomorphic	06	09.09
Amorphous	03	04.54

Table-11: Distribution of patients based on overlying skin

Overlying skin	Number	Percentage (%)
Normal	61	92.42
Skin retraction	03	04.55
Skin thickening	02	03.03

Table-12: Distribution of patients based on nipple retraction

Nipple retraction	Number	Percentage (%)
Yes	04	06.06
No	62	93.94

Table-13: Distribution of patients based on mammographic grade of lesion (BI-RADS)

Mammographic grade of lesion	Number	Percentage (%)
Benign	30	45.45
Probably benign	10	15.15
Suspicious of malignancy	17	25.76
Highly suspicious of malignancy	09	13.64

ULTRASONOGRAPHIC CHARACTERISTICS

Table-14: Distribution of patients based on shape of lesion

Shape of lesion	Number	Percentage (%)
Oval	34	51.52
Round	32	48.48

Table-15: Distribution of patients based on margin of lesion

Margin of lesion	Number	Percentage (%)
Circumscribed	36	54.55
Indistinct	10	15.15
Microlobulated	14	21.21
Spiculated	06	09.09

Table-16: Distribution of patients based on echogenicity

Echogenicity	Number	Percentage (%)
Anechoic	21	31.82
Hypoechoic	38	57.57
Isoechoic	01	01.52
Hyperchoic	01	01.52
Complex cystic	05	07.57

Table-17: Distribution of patients based on posterior echo intensity

Posterior Echogenicity	Number	Percentage (%)
Post acoustic enhancement	18	27.27
Shadowing	16	24.24
No posterior features	32	48.49

Table-18: Distribution of patients based on longitudinal versus anteroposterior diameter ratio

Longitudinal versus anteroposterior diameter ratio	Number	Percentage (%)
Yes	38	57.58
No	28	42.42

Table-19: Distribution of patients based on overlying skin

Overlying skin	Number	Percentage (%)
Normal	59	89.39
Skin retraction	06	09.09
Skin thickening	01	01.52

Table-20: Distribution of patients based on underlying muscle and chest wall

Underlying muscle and chest wall	Number	Percentage (%)
No infiltration	64	96.97
Infiltration	02	03.03

Table-21: Distribution of patients based on ultrasonography grade of lesion (BI-RADS)

Ultrasonography grade of lesion (BI-RADS)	Number	Percentage (%)
Benign	38	57.58
Probably benign	15	22.73
Suspicious of malignancy	05	07.57
Highly suspicious malignancy	08	12.12

Table-22: Distribution of patients based on FNAC report

FNAC report	Number	Percentage (%)
Benign	50	75.76
Malignant	16	24.24

Table-23: Comparison of mammographic BI-RADS with FNAC for benign & malignant breast lesions.

Parameters	Benign	Malignancy
Positive predictive value	76.00	61.54
Negative predictive value	24.00	38.46
Sensitivity	81.81	75.75
Specificity	71.00	59.00

Table-24: Comparison of ultrasonography BI-RADS with FNAC for benign & malignant breast lesions.

Parameters	Benign	Malignancy
Positive predictive value	97.09	97.09
Negative predicative value	02.91	02.91
Sensitivity	86.00	95.45
Specificity	95.45	86.75

Table-25: Combined mammography & ultrasonography BI-RADS with FNAC for benign & malignant breast lesions.

Parameters	Benign	Malignant
Sensitivity	94.20	96.41
Specificity	97.09	92.20

Table-26: Distribution of patients based age with FNAC report

Age	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
30-40 years	26	52.00	3*	18.75
41-50 years	20	40.00	6*	37.50
51-60 years	2	04.00	5	31.25
61-70 years	2	04.00	2	12.50
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.3: Distribution of patients based age with FNAC report

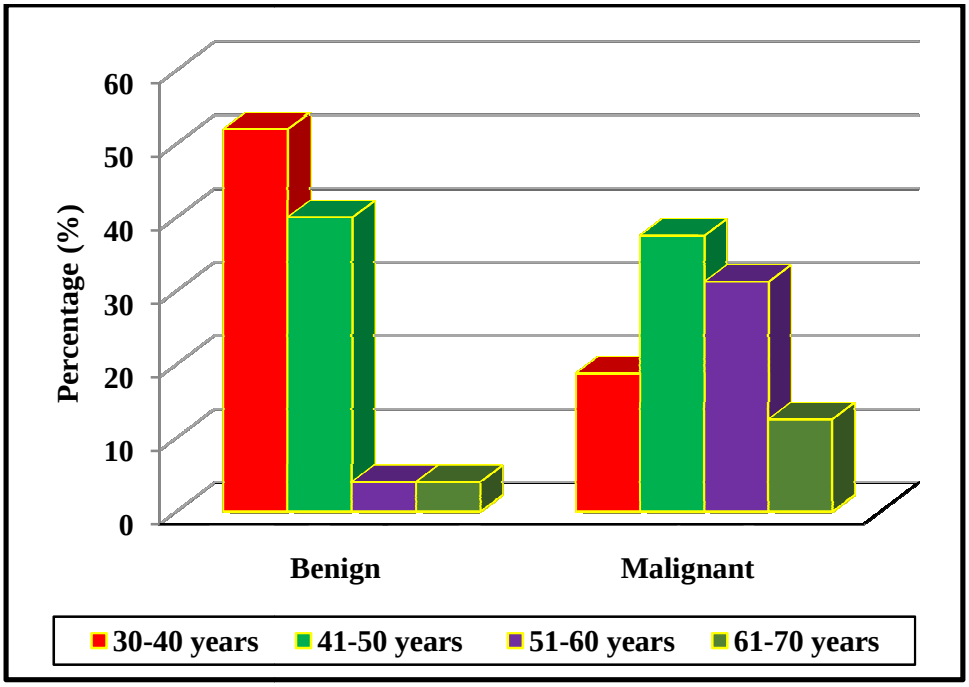


Table-27: Distribution of patients based on lesion density with FNAC report

Density	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
High density	47	94.00	16*	100.00
Low density	2	04.00	0	00.00
Fat containing	1	02.00	0	00.00
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.4: Distribution of patients based on lesion density with FNAC report

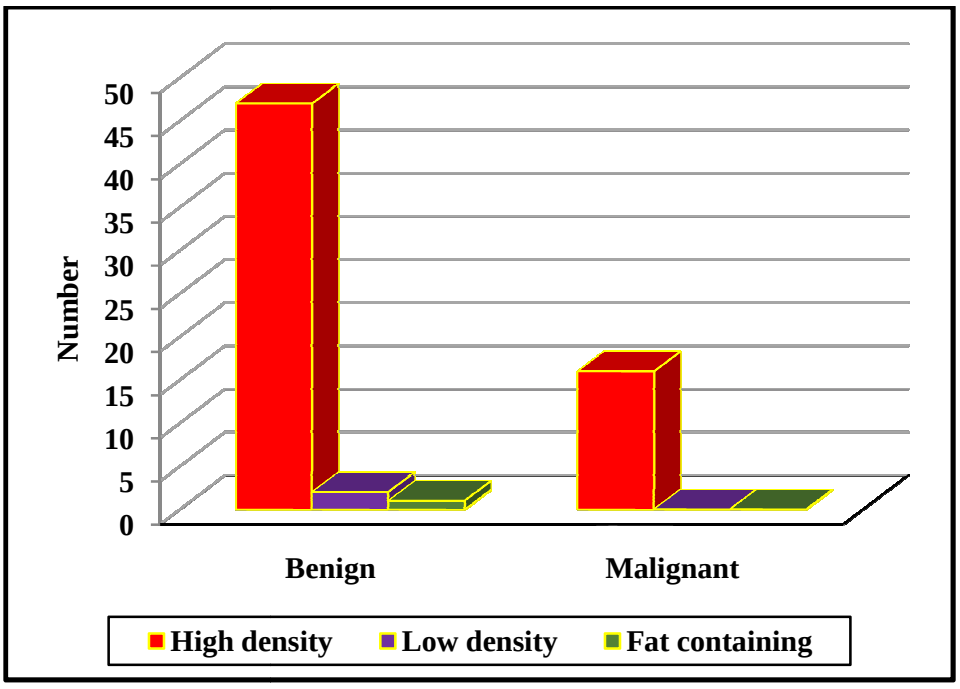


Table-28: Distribution of patients based on location with mammography

Location	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Upper outer quadrant	26	52.00	3*	18.75
Upper inner quadrant	7	14.00	2*	12.50
Lower inner quadrant	4	08.00	3	18.75
Lower outer quadrant	3	06.00	3	18.75
Central(Retroareolar)	10	20.00	5*	31.25
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.5: Distribution of patients based on location with mammography

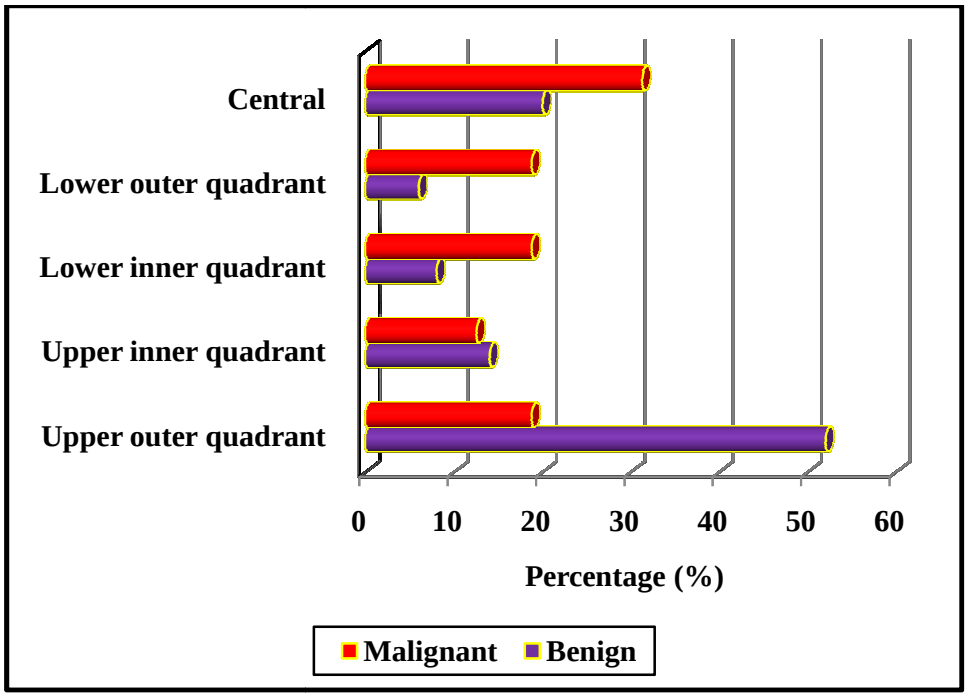


Table-29: Distribution of patients based on shape with mammography

Shape of lesion	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Oval	32	64.00	1*	06.25
Round	18	36.00	15*	93.75
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.6: Distribution of patients based on shape with mammography

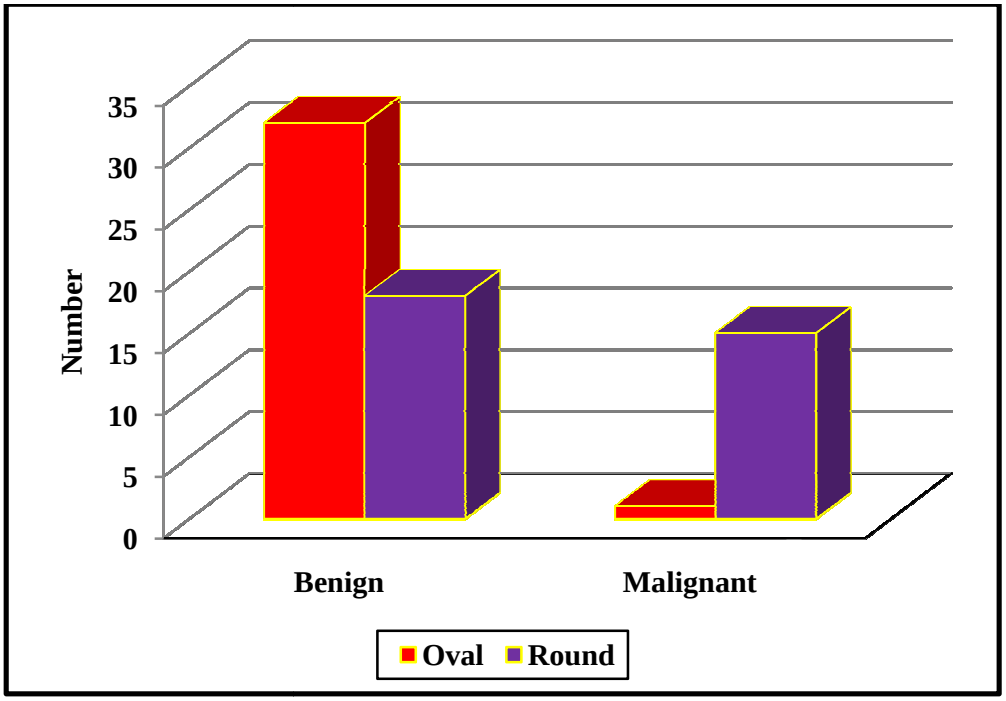


Table-30: Distribution of patients based on margin with mammography

Margin of lesion	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Well defined	39	78.00	1*	06.25
Microlobulated	7	14.00	4	25.00
Indistint	4	08.00	5	31.25
Spiculated	0	0.00	6*	37.50
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.7: Distribution of patients based on margin with mammography

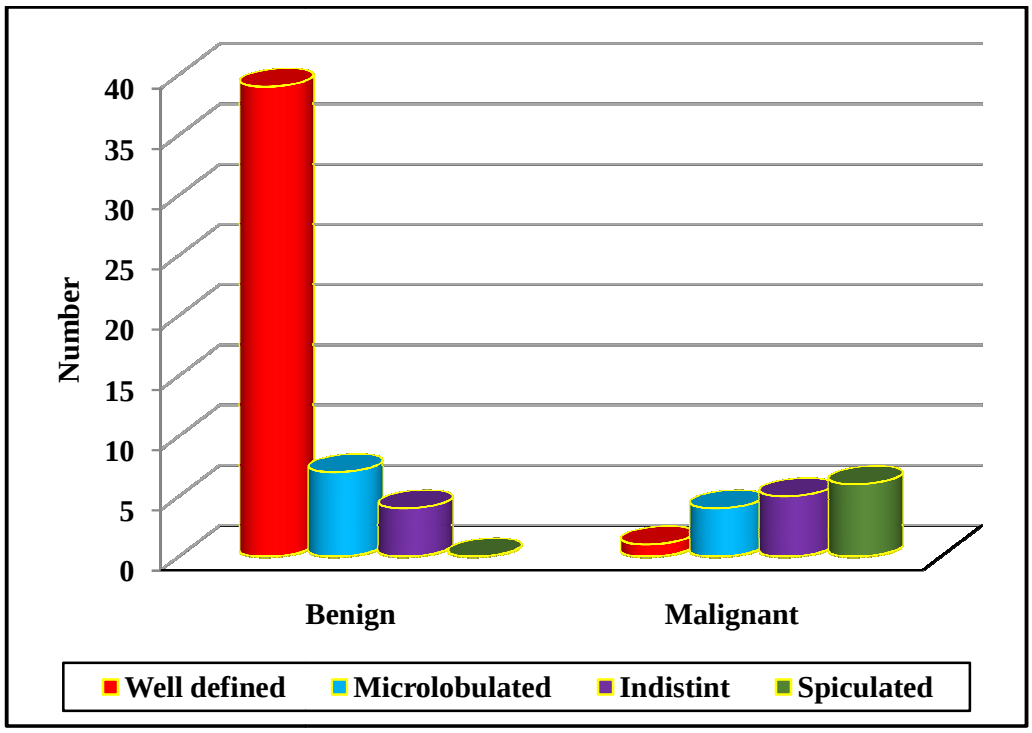


Table-31: Distribution of patients based on calcification of lesion with mammography

Calcification	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
None	45	90.00	9*	56.25
Coarse	2	04.00	0	00.00
Fine pleomorphic	0	00.00	7*	43.75
Amorphous	3	06.00	0	00.00
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.8: Distribution of patients based on calcification of lesion with mammography

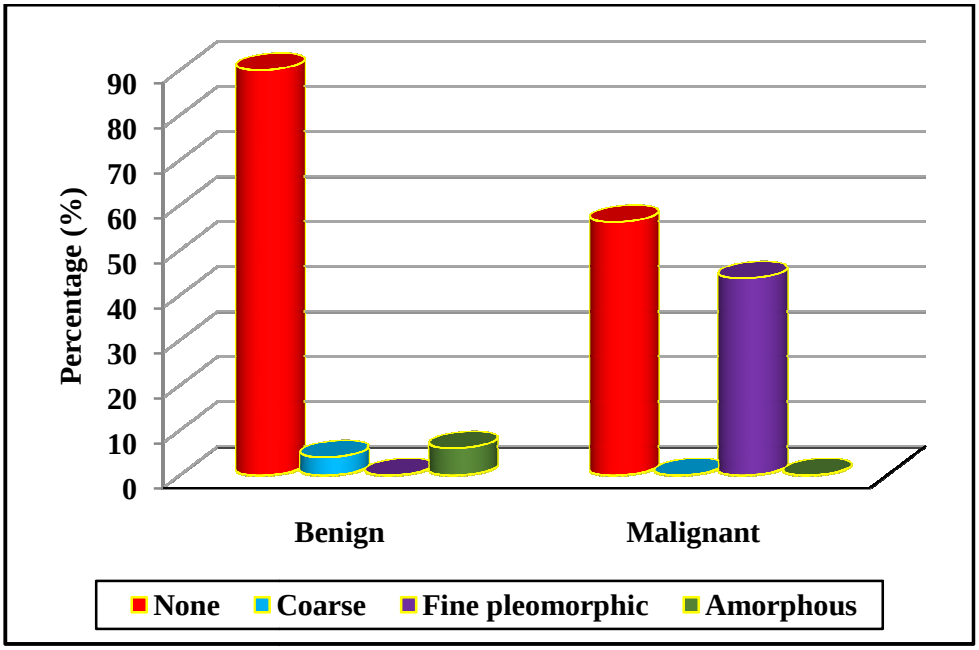


Table-32: Distribution of patients based on shape with ultrasonography.

Shape of lesion	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Oval	32	64.00	0*	00.00
Round	18	36.00	16	100.00
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.9: Distribution of patients based on shape with ultrasonography.

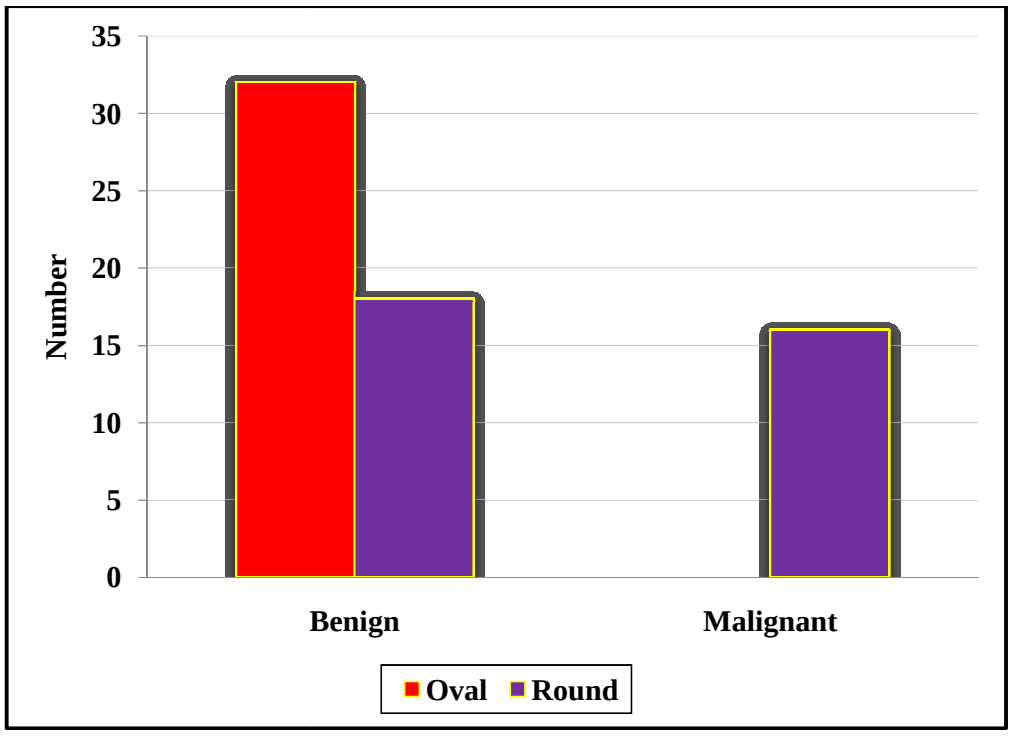


Table-33: Distribution of patients based on margin with ultrasonography.

Margin of lesion	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Circumscribed	36	72.00	0*	00.00
Indistinct	8	16.00	2*	12.50
Microlobulated	6	12.00	7	43.75
Spiculated	0	00.00	7*	43.75
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.10: Distribution of patients based on margin with ultrasonography

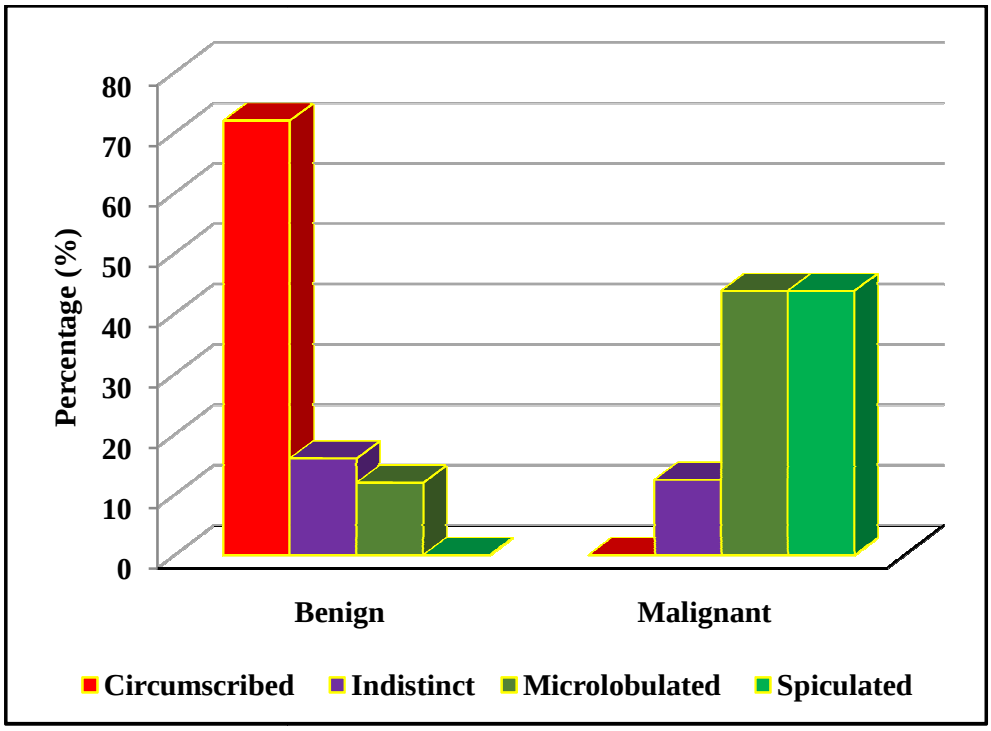


Table-34: Distribution of patients based on echogenicity with ultrasonography.

Echogenicity	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Anechoic	24	48.00	0*	00.00
Hypoechoic	21	42.00	14*	87.50
Isoechoic	1	02.00	0	00.00
Hyperchoic	1	02.00	0	00.00
Complex cystic	3	06.00	2	12.50
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.11: Distribution of patients based on echogenicity with ultrasonography

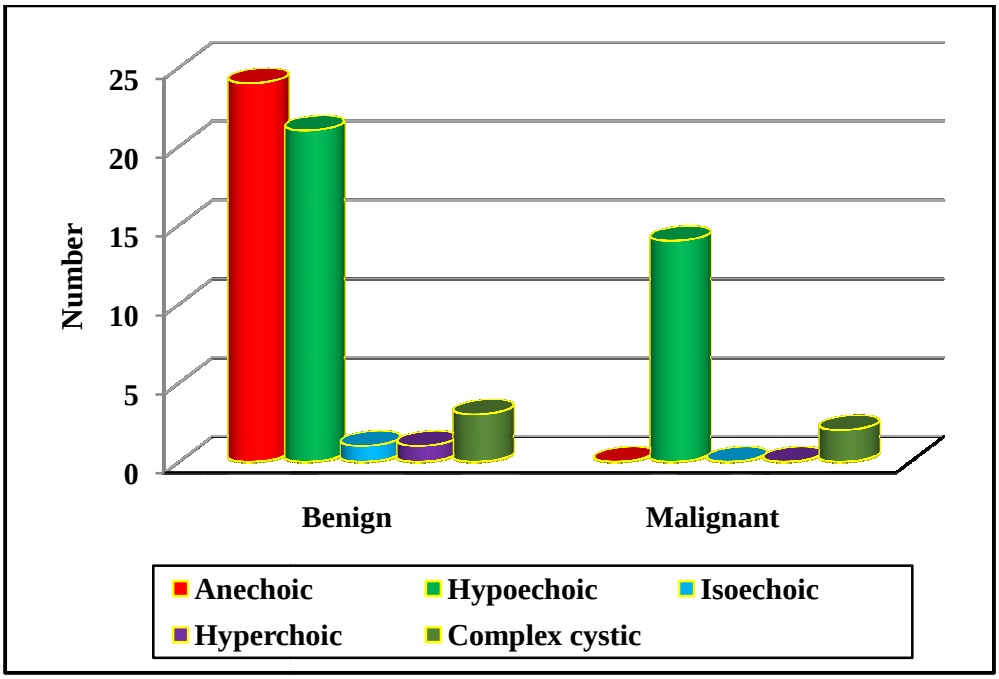
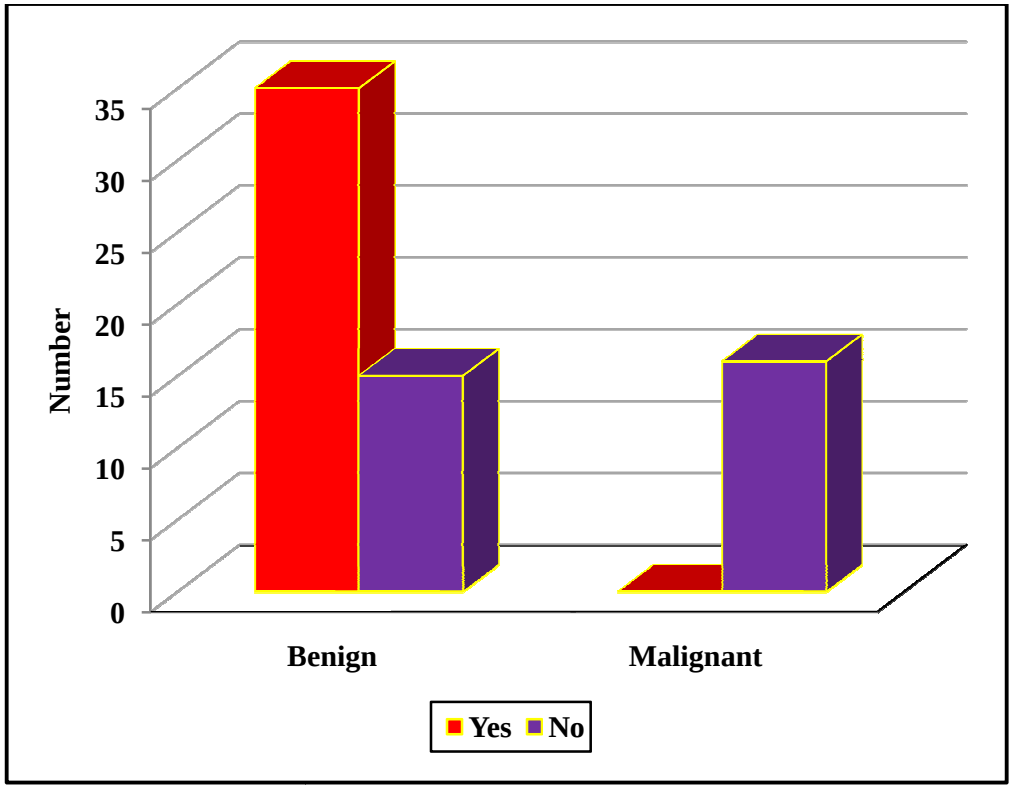


Table-35: Distribution of patients based on longitudinal versus anteroposterior diameter ratio with ultrasonography

Longitudinal versus anteroposterior diameter ratio	Benign		Malignant	
	Number	Percentage (%)	Number	Percentage (%)
Yes	35	70.00	0*	00.00
No	15	30.00	16	100.00
Total	50	100.00	16	100.00

(*p<0.05 significant compared benign with malignant)

Fig.12: Distribution of patients based on longitudinal versus anteroposterior diameter ratio with ultrasonography.



Discussion

DISCUSSION

This is a cross-sectional study completed during a period of one year in the Department of Radiodiagnosis, Sree Mookambika Institute of Medical Sciences, Padanilam, Kulasekharam, Kanyakumari District. A total of 66 females who were found to be have breast lesions and had positive findings on both mammography and ultrasonography with valid consent were included in the study.

The highest percentage of patients with lesions positive for malignancy was in the age group ranging from 41-60 years which accounted to 68.7%. Upper outer quadrant was the most common site for breast lesions having a total of 43.9%. 52% of the benign lesions were found in upper outer quadrant and the central (retroareolar) quadrant had the highest percentage (31%) for malignant lesions.

All the proven malignant lesions were round in shape on USG in our study. All the lesions having pleomorphic type of calcification (43%) on mammogram were positive for malignancy, which indicated that pleomorphic type of calcification was one of the criteria in grading a lesion malignant on imaging.

In a study conducted by Wendie et al. showed that pleomorphic calcification seen within a mass was mostly proven on histopathology to be a typically invasive ductal carcinoma.[33] 56% of the breast lesions without

any calcification were positive for malignancy from which we could conclude that not all breast malignancies had calcifications.

In my study, all the lesions which had a longitudinal versus anteroposterior diameter ratio of more than one were benign and those not fulfilling the criteria were almost equally either benign or malignant. From this we could say that a lesion having a longitudinal versus AP diameter of more than 1 was definitely benign and rest of the lesions could be either benign or malignant. All well-circumscribed lesions on ultrasonography were proven to be benign. In a similar study by Luciano Chala et al., a round lesion with well-circumscribed margins, a longitudinal versus AP diameter ratio which was greater than or equal to 1.0 and no hypoechogenicity, with no obvious microcalcifications when seen were most probably considered benign lesion ultrasonogrphy.[16]

All lesions with spiculated margins on mammography, i.e. 37% and ultrasonography, i.e. 43% were found to be positive for malignancy and few of the lesions with microlobulations were malignant. Three of the cases that were given a grade of BI-RADS 5 had positive malignant ipsilateral lymph nodes, which were enlarged with loss of fatty hilum in our study. None of the cases of BI-RADS 2 & 3 were malignant on mammography.

In our study, the positive predictive value was 76% and the negative predictive value was 24% for benign lesions while the PPV was 61.5% and

the NPV was found to be 38.4% for malignant lesions on mammography. Mammographic BI-RADS with FNAC was 81% sensitive and 71% specific for benign lesions, while the sensitivity was 75.7% and the specificity was 59% for malignant lesions.

Positive predictive value (PPV) was 97% for ultrasonographic categorization of BI-RADS lesions with FNAC correlation for both benign and malignant lesions. Ultrasonographic BI-RADS with FNAC was 86% sensitive and 95% specific for benign lesions, while the sensitivity was 95% and the specificity was 86% for malignant lesions.

This is comparable with several other studies where PPV of BI-RADS 4 lesions ranged from 16-52.7% and PPV of BI-RADS 5 ranged from 68-100%.[87-89] Taplin et al.[87] described a PPV of BI-RADS category 4 as 16.7% and a PPV of BI-RADS category 5 as 68.4%. Another study by Zonderland et al. reported PPV of BI-RADS category 4 as 52.7% and a BI-RADS category 5 as 100% in a screening population.[88] In a recent study by Timmers et al., PPV of BI-RADS 4 was 39.1% and of BI-RADS 5 was 92.9%.[89]

Moss et al. reported that ultrasonography increased cancer detection by 14% in symptomatic patients who were evaluated with both mammography and ultrasonography.[90] In retrospective analysis of 293 palpable malignant lesions, ultrasonography detected all cancers; 18(6.1%) of these 293 cancers were mammographically occult.[91]

Both the modalities (mammography & ultrasonography) combined with FNAC yielded the best results with the sensitivity of 94% for benign lesions and 96% for malignant lesions, while the specificity was 97% for benign lesions and 92% for malignant lesions.

The specificity and sensitivity was more accurate when both the modalities were combined in our study group. Our results were slightly different from other studies which evaluated the sensitivity of radiological grading in predicting malignancy.

Phurailatpam et al.[4] had described in women > 30 years of age the mammographic evaluation with FNAC was 92.3% sensitive, 91.8% specific, 85.7% was the positive predictive value and 95.7% was the negative predictive value. Whereas the result with ultrasonograpic evaluation with FNAC was 80.7% sensitive, 100% specific, 100% was the positive predictive value and 90.7% was the negative predictive value.

The combination of the imaging modalities of mammography and ultrasonography gave a sensitivity of 92.3%, specificity 100%, positive predictive value 100% and 96% was the negative predictive value. It was concluded that combined imaging modalities of ultrasonography and mammography yielded a better result than with either imaging modalities on its own thereby helping in more accurate characterization of lesions in the breast.

Zonderland et al. described an overall sensitivity of 85% and specificity of 98.7%. The sensitivity of diagnostic examinations in the study was 92.9% and specificity 97.7%, whereas that of screening examinations was 69.2% and specificity 99.2% with combination of both USG and mammography. [88]

Conclusion

CONCLUSION

Breast ultrasound is more accurate than mammography in women who are young. In women with dense breasts, ultrasound appeared to be superior to mammography and could be used as an appropriate initial imaging test in those women. The accuracy of mammograms increased with fatty breasts in older age group.

The definitive features of benign and malignant lesions were correlating with FNAC, so if the lesion is found to be 100% benign (BI-RADS 2 category) in USG and mammography, FNAC may be avoided. All the lesions which were detected as BI-RADS 5 in either USG or mammography or both were found to be 100 % malignant. USG could detect almost all the malignant lesions except in three of the cases.

Combined USG and mammography yielded the best result and can be used as a screening modality to detect malignancy earlier and to treat the patient earlier.

Summary

SUMMARY

In this study, the accuracy of radiological grading and FNAC was evaluated in cases of mammographically and ultrasonographically detected breast lesions.

By use of concordant mammographic, ultrasonography and FNAC results, we could correlate each modality with FNAC results and concluded that the most accurate method was when both the modalities were combined to give BI-RADS grading.

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Appendices

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES
KULASEKHARAM

RESEARCH COMMITTEE

CERTIFICATE

This is to certify that the Research Protocol Submitted by Mahtab Yeganegi

~~*Faculty*~~ */ Post Graduate from Department of* Radiodiagnosis

Titled "Mammogram and ultrasound evaluation of breast lesions with FNAC correlation"

is approved by the Research Committee.

27/1/15

Chair Person

Prof. & H.O.D.
Dept. of Bio-Chemistry
Sree Mookambika Institute of Med
Kulasekharam

Convenor

Prof. & H.O.D.
Dept. of Physiology
Sree Mookambika Institute of Medical Sciences
Kulasekharam 629 161

Date : 27/1/15

Sree Mookambika Institute of Medical Sciences
Kulasekharam (K.K District, TN) 629161

Phone No: 04651-280866, Fax No. 04651-280740

Institutional Human Ethics Committee

Registered under CDSCO with Reg No. ECR/446/Inst/TN/2013

Ref. No. SMIMS/IHEC/2015/A/34 **Date: 10th April 2015**

Certificate

This is to certify that the Research Protocol Ref. No. **SMIMS/IHEC/2015/A/34**, entitled "Mammogram and Ultrasound Evaluation of Breast Lesions With FNAC Correlation" submitted by Dr. Mahtab Yeganegi, Postgraduate of Department of Radiodiagnosis, SMIMS has been approved by the Institutional Human Ethics Committee at its meeting held on 13th of March 2015.

[This Institutional Human Ethics Committee is organized and operates according to the requirements of ICH-GCP/GLP guidelines and requirements of the Amended Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945 of Government of India.]

SREE MOOKAMBIKA INSTITUTE OF MEDICAL SCIENCES * KULASEKHARAM * IHEC Date 10/4/15

Dr. Rema Menon. N
Member Secretary
Institutional Human Ethics Committee
Professor of Pharmacology and HOD
SMIMS, Kulasekharam [K.K District]
Tamil Nadu -629161

CONSENT FORM

PART 1 OF 2

INFORMATION FOR PARTICIPANTS OF THE STUDY

Dear Volunteers,

We welcome you and thank you for your keen interest in participating in this research project. Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain the nature, the purpose, the benefits, the risks, the discomfort, the precautions and the information about how this project will be carried out. It is important that you can read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you have any doubts or if you want more information, you are to ask the study personnel or the contact person mentioned below before you give your consent and also at any time during the entire course of the project.

1. **Name of the Principal Investigator** **:** Dr. Mahtab Yeganegi
   Postgraduate-M.D
   Radiodiagnosis
   SMIMS, Kulasekharam

2. **Name of the Guide** **:** Dr. G. Vijaya Kumar
   Professor and HOD
   Department of Radiodiagnosis
   SMIMS, Kulasekharam

3. **Name of the co-guide** **:** Dr. S. Sathish Babu
   Associate Professor
   Department of Radiodiagnosis
   SMIMS, Kulasekharam

4. **Name of the co-guide** **:** Dr. Jayasree P.V
   Professor
   Department of Pathology
   SMIMS, Kulasekharam

5. **Institute: details with Address :** Sree Mookambika Institute of Medical Sciences,
Kulasekharam -629161
Kanyakumari District, Tamil Nadu

6. **Title of the study:**

"Mammogram and Ultrasound Evaluation of Breast Lesions with FNAC Correlation"

7. **Background Information:**

Mammogram evaluation is typically limited to breast lesions with ultrasound being an adjunct to it. Many studies have been conducted to find the sensitivity and specificity of role of mammogram and ultrasound in evaluating and grading breast lesions with FNAC correlation.[17]

8. **Aims and Objectives:**

1. To study the mammographic and ultrasonographic characteristics of breast lesions in patients.
2. To categorize the detected breast lesions according to BI-RADS.
3. To correlate the categorized breast lesions (BI-RADS) with FNAC.
4. To compare the sensitivity of mammography with ultrasonography in diagnosing benign and malignant breast lesions.

9. **SCIENTIFIC JUSTIFICATION OF THE STUDY:**

Early detection and improved treatment is required to decrease breast cancer related deaths. The effective diagnosis and management of breast lesions involves multidisciplinary approach to their assessment. Non-invasive techniques such as mammography, is a well-defined and widely accepted radiologic procedure to evaluate clinically suspected breast lesions and as a tool to screen for breast cancer. However, the appearance of overlapping tissue on mammograms poses a significant obstacle to interpretation. Hence, ultrasonography is an adjunctive modality, especially in patients with dense

breasts and it also helps to characterize an undetected abnormality on mammography. Combining both the modalities (mammography and ultrasonography) yielded the best results. Ultrasonography and mammography diagnosed lesions, were confirmed by FNAC. As FNAC is an invasive procedure, imaging modalities that can detect and grade the lesion according to BI-RADS, will reduce the requirement of subjecting the patient to invasive procedures especially in definitively benign lesions.[1, 2]

10. Procedure of the study:

After getting a valid consent from the patient, she will undergo the following:

1. Conventional mammography, will be obtained for both the breasts.
2. Sonomammography will be done for both the breasts.
3. Ultrasound guided fine needle aspiration cytology will be done and the obtained material will be sent for pathological examination.

After all the tests, the BIRADS score and FNAC will be correlated for the study purposes.

11. Expected risk of the participants: The risks of the procedure are minimal. One risk is mild pain at time of FNAC procedure and another risk is minor bleeding which may occur in the lesion or under the skin and may result in swelling, bruise and mild discomfort. This generally is limited if firm pressure is applied to the aspirated site.

12. Expected Benefits of the Research for the participants: To detect any breast lesions in its initial stages.

13. Maintenance of confidentiality:

All data collected for the study will be kept confidentially. No personal details will be revealed.

14. Why have I been chosen to be in this study: you are in the age group for breast lesion and fulfill the criteria for selection.

15. How many people will be in the study : 66

16. Agreement of compensation to the participants : No

17. **Anticipated prorated payment, if any, to the participants of the study :** Nil

18. **Can I withdraw from study at any time during the study period :** Yes

19. If there is any new finding/information, would I be informed : Yes

20. Expected duration of the participants participation in the study : Single visit.

21. Any other pertinent information : No

22. Whom do I contact for further information:

For any study related queries, you are free to contact

Dr Mahtab Yeganegi
Post Graduate – M.D Radiodiagnosis
Department of Radiodiagnosis
Sree Mookambika Institute of Medical Sciences,
Kulasekharam, Tamil Nadu -629161
Mobile Number: +919787894958
e-mail I.D: mahtabyeganegi@gmail.com

Place:

Date:

Signature of Participant **Signature of Principal Investigator**

CONSENT FORM

PART 2 OF 2

PARTICIPANTS CONSENT FORM

The details of the study have been explained to me in writing and details have been fully explained to me. I am aware that the results of the study may not be directly beneficial to me but will help in the advancement of medical sciences. I confirm that I have understood the study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reasons, without the medical care that normally is provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have given details of the study. I fully consent to participate in the study titled “Mammogram and Ultrasound Evaluation of Breast Lesions with FNAC Correlation”

Serial no/Reference no:

Signature of the patient: Signature of the investigator:

Address of the patient: Address of the investigator:

Signature of the witness:

Address of the witness:

Date:

Place:

PROFORMA

1) Serial no:

2) Date:

3) Name:

4) Age in years:

5) Address & Phone no:

6) Family history of breast cancer: [01- Yes 02- No]

7) Indication for Mammogram
[01-Screening 02-Pain 03-Lump 04- Nipple discharge]

8) Side of lesion [01- Right 02- Left]

XRAY MAMMOGRAPHIC FINDINGS:

9) Class of breast density:
[01-Predominantly fatty 02-Fibrofatty
03-Heterogenously dense 04-Extremely dense]

10) Location
[01-Upper outer quadrant 02-Upper inner quadrant
03-Lower inner quadrant 04-Lower outer quadrant
05-Central]:

11) Shape of lesion
[01-oval 02- round]

12) Margin of lesion
[01-well defined 02-microlobulated
03-indistint 04-spiculated]

13) Density
[01-high density 02-low density 03- fat containing]

14) Calcification
[01-none 02-coarse 03-fine pleomorphic 04-amorphous]

15) Overlying skin
[01-normal 02-skin retraction 03-skin thickening]

16) Nipple retraction
[01-Yes 02-No]

17) Mammographic grade of lesion, BIRADS:
[01-negative 02-benign 03-probably benign
04-suspicious of malignancy 05-highly suspicious of malignancy]

SONOMAMMOGRAPHIC CHARACTERISTICS

18) Shape of lesion
[01-oval 02- round]

19) Margin of lesion
[01-circumscribed 02- indistinct
03- microlobulated 04 - spiculated]

20) Echogenicity
[01-Anechoic, 02-Hypoechoic, 03-Isoechoic
04-Hyperechoic 05- Complex cystic and solid].

21) Posterior Echo Intensity-
[01-Post acoustic Enhancement
02-Shadowing 03-no posterior features].

22) Longitudinal versus anteroposterior diameter ratio > or =1.0.
[01- Yes 02- No]

23) Overlying Skin
[01-normal 02- skin retraction 03- skin thickening].

24) Underlying Muscle and Chest wall
[01- no infiltration 02- infiltration].

25) Sonomammography grade of lesion, BIRADS:
[01-negative 02-benign 03-probably benign
04-suspicious of malignancy
05-highly suspicious of malignancy]

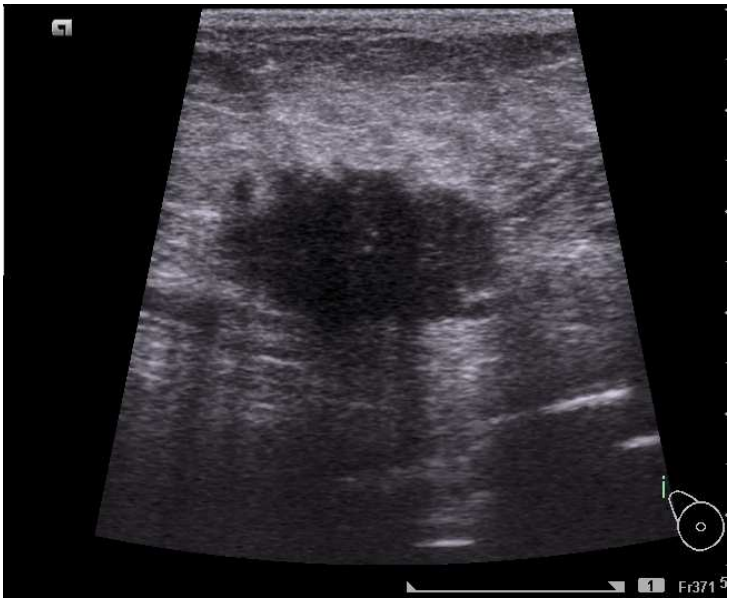
26) FNAC report
[01-Benign 02-Malignant]

LIST OF ABBREVIATIONS USED

- ACR — American College of Radiology
- AJCC — American Joint Committee on Cancer
- AP — Antero-posterior
- BI-RADS — Breast Imaging Reporting and Data System
- CC — Craniocaudal
- CAD — Computer aided detection
- DCIS — Ductal Carcinoma In-Situ
- FNAC — Fine Needle Aspiration Cytology
- 3D — Three- Dimensional
- IDC — Invasive Ductal Carcinoma
- MIP — Maximum Intensity Projection
- MLO — Mediolateral oblique
- MRI — Magnetic Resonance Imaging
- NPV — Negative predictive value
- PPV — Positive predictive value
- STIR — Short Tau Inversion Recovery
- TNM — Tumour, Node, Metastasis
- T1W — T1-weighted
- T2W — T2-weighted
- USG — Ultrasonography

CASE 1

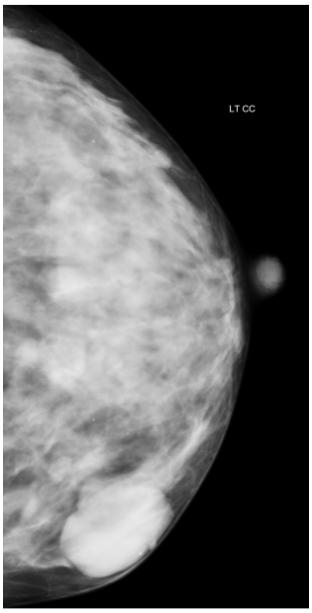
Radiopacity noted in the retroareolar region with spiculated margins - BIRADS V



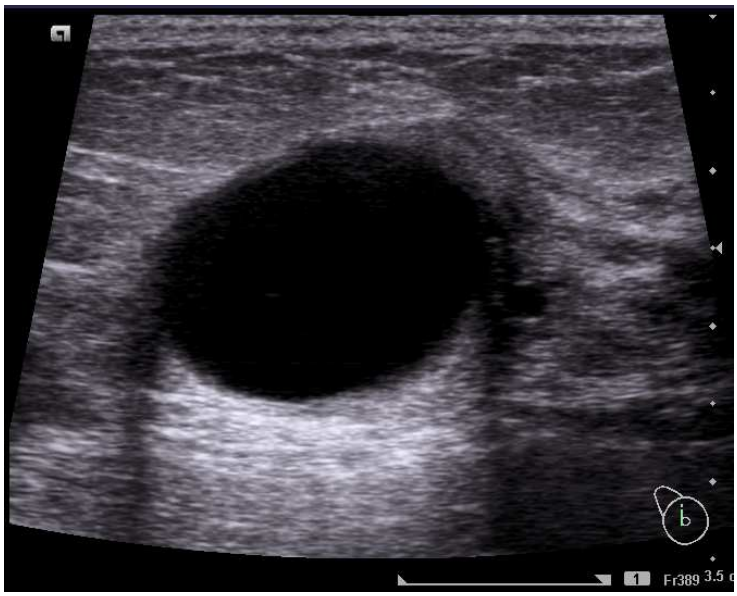
USG of same patient shows an ill-defined, spiculated, hypoechoic, taller than wide mass lesion -BIRADS V

FNAC - positive for malignant cells from ductal carcinoma - intermediate nuclear grade.

CASE 2



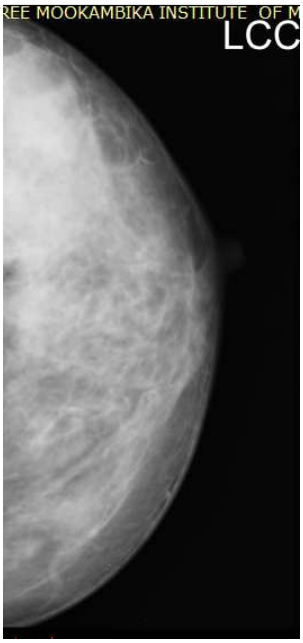
A well-defined, smooth margin radiodense opacity is seen in the lower inner quadrant of left breast - BIRADS II.

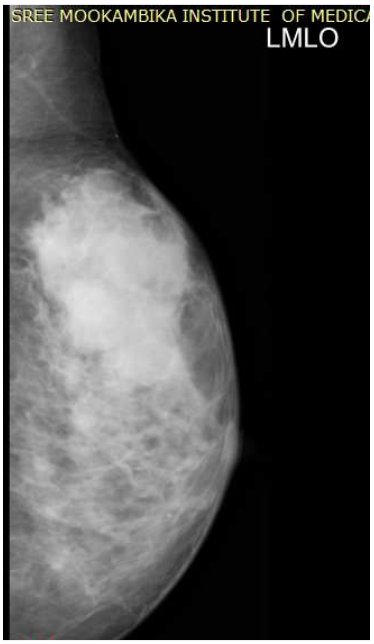


A well defined, rounded anechoic lesion seen with posterior acoustic enhancement - simple cyst BIRADS 2.

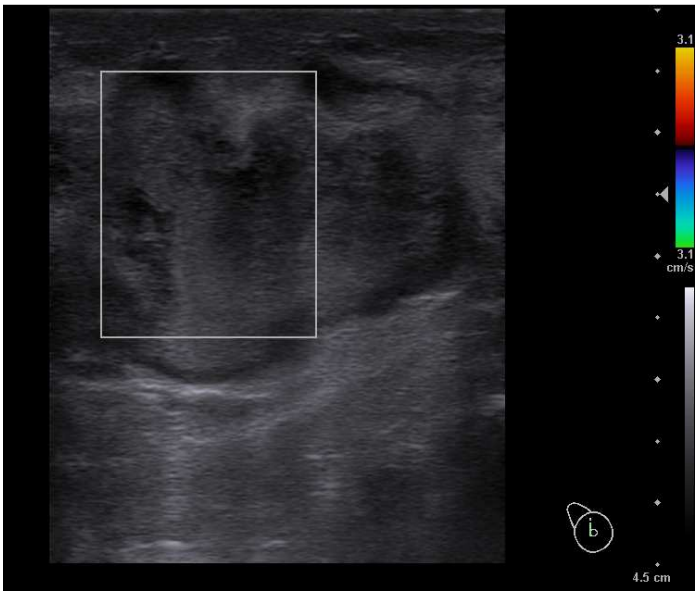
FNAC - benign epithelial lesion with cystic change.

CASE 3





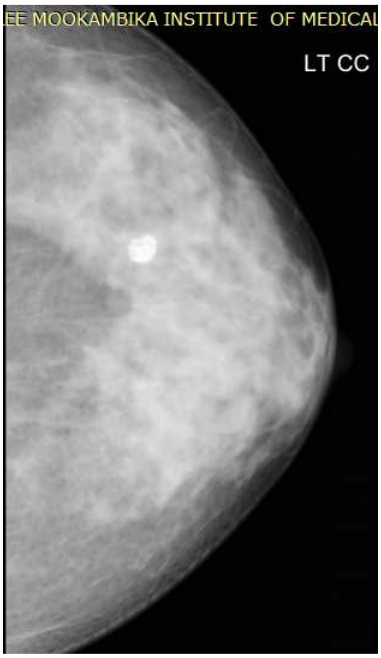
An ill-defined radiopacity noted in the upper outer quadrant of left breast. No calcification / fat density noted within - BIRADS IV.

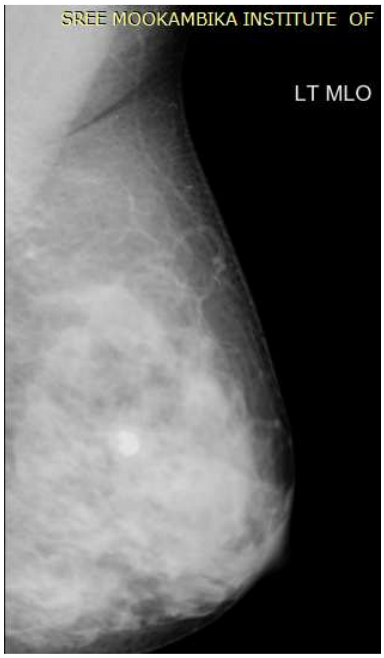


Lobulated, moderately thick walled cystic lesion with thick internal echoes - BIRADS IV.

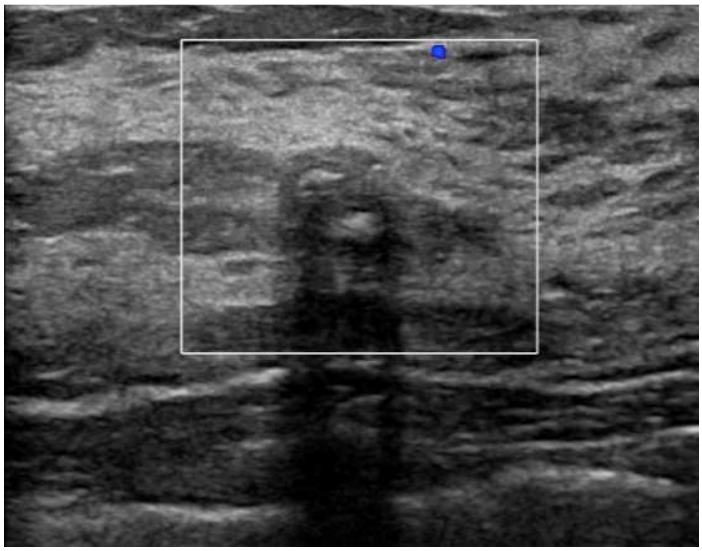
FNAC - suppurative inflammatory lesion.

CASE 4





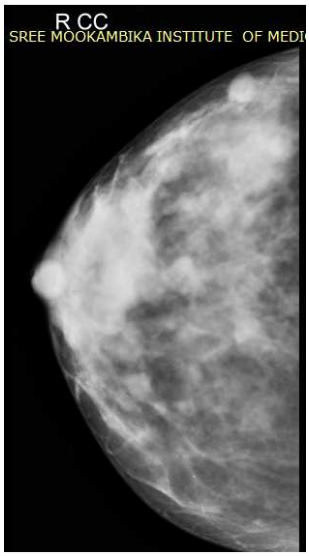
Calcified fibroadenoma is noted in the upper outer quadrant of left breast - BIRADS II.

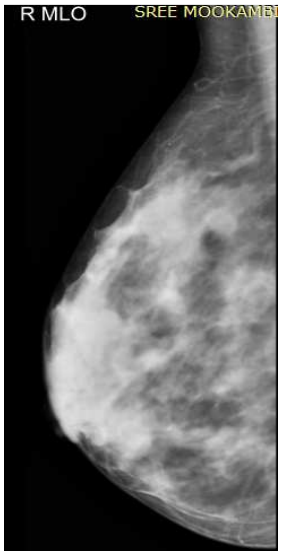


USG showed hypoechoic lesion with calcification - BIRADS II (Involuted fibroadenoma).

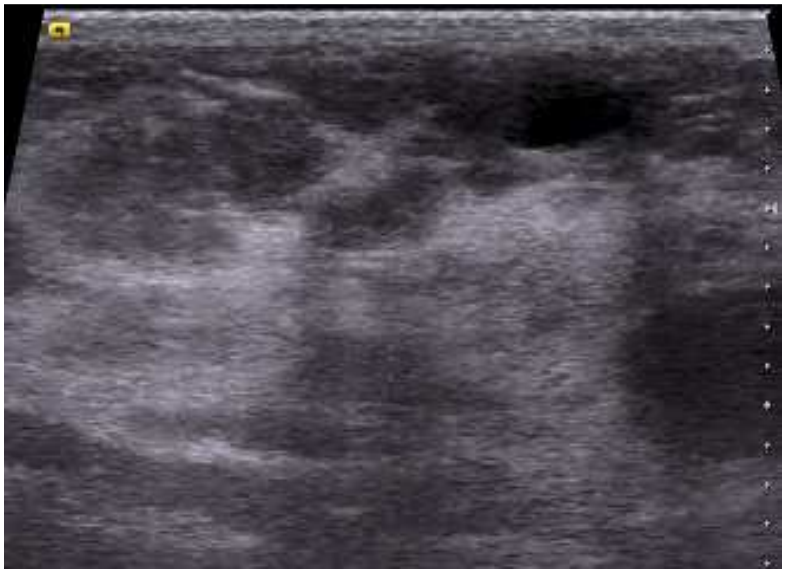
FNAC - showed benign proliferative fibroepithelial cells.

CASE 5





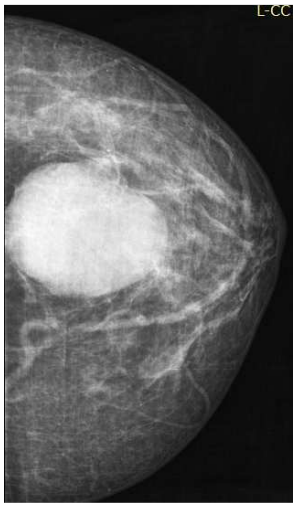
Well-defined, round radiodense opacity with smooth margins is noted in the upper outer quadrant of right breast - BIRADS III



A well-defined, oval shaped anechoic lesion with posterior acoustic enhancement – BIRADS II.

FNAC - benign epithelial lesion with cystic change.

CASE 6

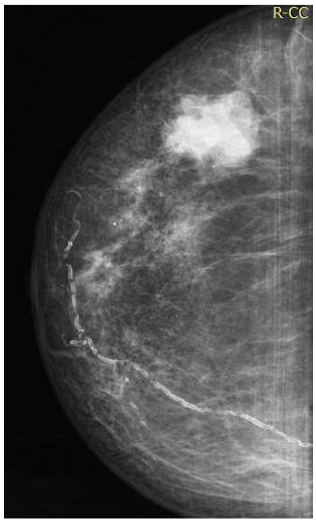


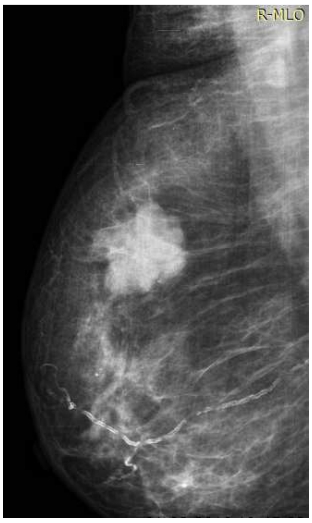
A well-defined, radiodense opacity with lobulated margins is seen in the left retroareolar region - BIRADS IV

A well-defined complex solid cystic lesion with no calcification seen - BIRADS IV

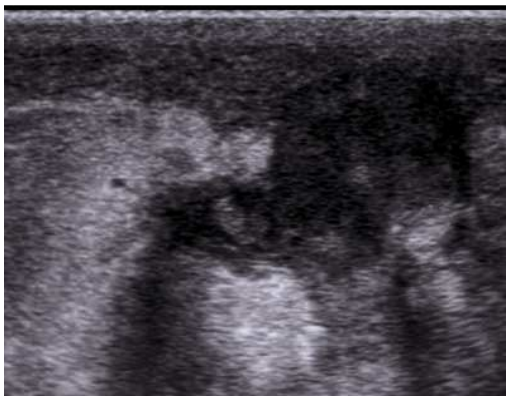
FNAC - benign fibroepithelial cells seen.

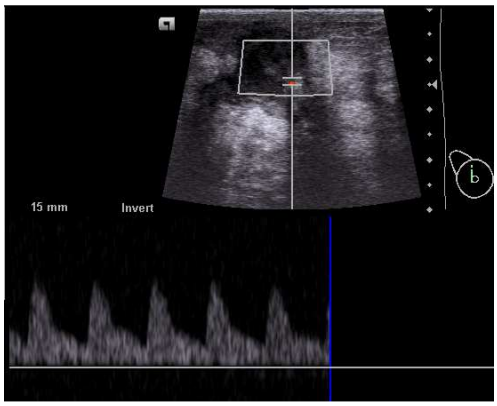
CASE 7





Lobulated, homogenous radiopacity with irregular margins is noted in the upper outer quadrant of right breast - BIRADS V
Vascular calcification seen.

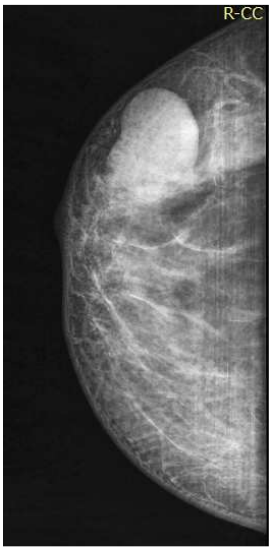




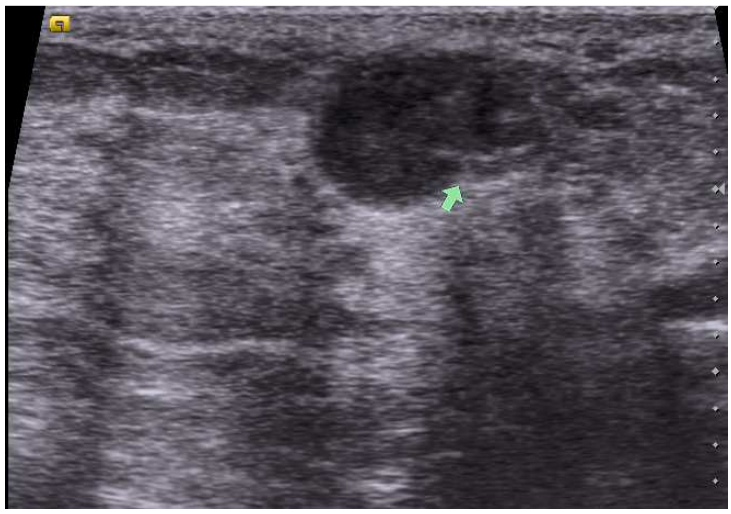
Heterogeneously hypoechoic solid mass with irregular margin noted in right breast. Anteroposterior diameter is greater than the transverse diameter and shows vascularity within - BIRADS V

FNAC - positive for malignant cells.

CASE 8



A welll-defined, lobulated radioopacity is noted in the right upper outer quadrant - BIRADS IV



USG - A well-defined, lobulated outline hypoechoic lesion is seen with mild posterior acoustic enhancement. The lesion is wider than tall - BIRADS IV

FNAC - atypical cells seen - possibly malignant.

MASTER CHART

S. No	Age (Y)	F. B.C	Indica	B Density	Location	Shape	Margin	Lesion density	Calcification	Overlying skin	Nipple retraction	Mammo-BIRADS
1	55	2	3	3	1	2	1	1	4	1	2	2
2	45	2	1	2	5	2	2	1	1	1	2	3
3	44	2	3	2	5	2	1	1	1	1	2	2
4	40	1	3	2	5	2	4	1	1	1	2	5
5	58	2	2	2	5	1	3	2	1	1	2	4
6	48	2	3	2	1	1	1	1	1	1	2	2
7	36	1	3	3	2	1	1	1	1	1	2	3
8	33	2	2	3	5	2	1	1	1	1	2	4
9	32	2	3	3	2	1	1	1	1	1	2	2
10	45	1	1	3	1	1	1	2	1	1	2	2
11	43	2	1	3	1	2	1	1	1	1	2	2
12	43	3	1	3	1	1	1	1	1	1	2	3
13	40	2	1	2	1	1	1	1	1	1	2	2
14	48	1	2	2	5	2	3	1	1	1	2	4
15	42	2	3	2	1	1	2	1	1	1	2	3
16	38	2	4	3	5	2	3	1	4	1	2	4
17	36	2	3	2	2	1	2	1	1	1	2	4
18	38	2	2	2	2	1	1	1	1	1	2	2
19	42	1	3	2	5	2	1	1	1	1	2	4
20	57	2	4	3	1	2	4	1	3	2	1	5
21	45	2	5	3	1	1	1	1	1	1	2	3
22	35	2	3	3	1	2	1	1	4	1	2	2
23	39	2	1	2	5	2	2	1	1	1	2	3

24	50	2	4	1	4	2	4	1	3	1	1	5
25	45	2	1	2	2	1	1	1	1	1	2	2
26	63	1	3	1	3	2	4	1	3	3	2	5
27	42	2	3	2	1	2	3	1	1	1	2	4
28	35	2	1	3	1	1	1	1	1	1	2	2
29	50	2	3	1	1	1	1	1	1	1	2	4
30	42	2	3	1	1	1	1	1	1	1	2	4
31	45	2	3	2	1	1	1	1	1	1	2	4
32	60	2	3	1	3	2	1	1	1	1	2	4
33	39	2	1	2	1	1	1	1	1	1	2	2
34	65	1	4	1	2	2	3	1	1	1	2	5
35	33	2	3	2	4	1	1	1	1	1	2	2
36	53	2	4	1	5	2	3	1	1	2	2	5
37	40	2	2	2	1	2	1	1	1	1	2	2
38	48	2	3	1	5	2	1	1	1	1	2	2
39	44	2	3	2	3	2	2	1	3	1	2	2
40	48	1	4	1	5	2	3	1	1	2	1	5
41	43	2	2	2	1	2	3	1	1	3	2	4
42	33	2	3	2	2	2	1	1	1	1	2	3
43	31	2	2	3	1	1	1	1	1	1	2	2
44	44	2	2	1	1	1	1	1	1	1	2	2
45	31	2	3	2	3	2	1	1	1	1	2	4
46	30	2	2	3	5	1	2	1	2	1	2	3
47	63	1	1	1	4	1	1	1	1	1	2	3
48	34	2	2	2	1	2	1	1	1	1	2	4
49	66	2	2	1	2	1	1	1	1	1	2	3

50	32	2	3	3	5	1	2	1	1	1	2	4
51	31	2	3	2	3	1	1	1	1	1	2	2
52	43	2	2	2	3	2	1	1	1	1	2	2
53	48	1	2	2	1	2	1	1	1	1	2	2
54	47	2	3	1	1	2	1	1	1	1	1	2
55	35	2	3	2	4	1	1	1	1	1	2	2
56	40	2	1	1	1	1	1	1	1	1	2	2
57	30	2	2	4	1	1	1	3	1	1	2	2
58	42	2	3	2	2	1	1	1	1	1	2	2
59	31	2	2	2	1	1	1	1	1	1	2	2
60	49	2	3	2	1	2	4	1	1	1	2	5
61	60	2	4	1	4	2	2	1	3	1	2	5
62	36	1	2	2	3	1	1	1	1	1	2	2
63	55	2	3	1	3	2	3	1	3	1	2	4
64	45	2	1	2	1	1	1	1	1	1	2	2
65	38	1	4	2	5	2	1	1	1	1	2	4
66	39	1	1	3	1	1	1	1	1	1	2	2

S. No	US Shape	US Margin	Echogenicity	Post echo	Ratio	Overlying skin	Invasion muscle	Sono-BIRADS	FNAC
1	2	1	1	3	2	1	1	3	1
2	2	3	1	1	2	1	1	3	1
3	2	1	1	1	1	1	1	2	1
4	2	4	2	3	2	1	2	5	2
5	1	1	2	3	1	1	1	4	1
6	1	1	1	1	1	1	1	2	1
7	1	3	2	2	1	1	1	2	1
8	2	2	5	3	1	1	1	3	1
9	1	1	1	1	2	1	1	2	1
10	1	1	2	3	1	1	1	2	1
11	1	1	1	1	1	1	1	2	1
12	1	1	2	2	1	1	1	2	1
13	1	1	1	1	1	1	1	2	1
14	2	2	2	3	2	1	1	3	1
15	1	3	2	3	1	1	1	2	1
16	1	3	2	3	2	1	1	4	1
17	1	3	2	3	2	1	1	2	2
18	1	1	2	3	1	1	1	2	1
19	2	3	2	2	2	1	1	3	2
20	2	4	2	2	2	2	1	5	2
21	1	1	2	2	1	1	1	2	1
22	2	1	1	3	2	1	1	3	1
23	2	3	1	1	2	1	1	3	1
24	2	4	2	2	2	1	2	5	2
25	1	1	3	3	1	1	1	2	1

26	2	4	2	2	2	2	1	5	2
27	2	2	2	3	1	1	1	3	1
28	1	1	2	3	1	1	1	2	1
29	1	3	2	3	2	1	1	2	2
30	1	3	2	3	1	1	1	2	1
31	2	1	5	1	2	1	1	3	1
32	2	1	5	3	2	1	1	3	2
33	1	1	2	3	1	1	1	2	1
34	2	4	2	3	2	1	1	4	2
35	1	1	2	3	1	1	1	2	1
36	2	3	2	2	2	2	1	4	2
37	2	1	1	3	1	1	1	2	1
38	2	1	1	1	2	1	1	2	1
39	2	3	2	2	2	2	1	5	2
40	2	2	2	2	2	2	1	5	2
41	2	2	2	3	2	3	1	3	1
42	2	2	2	3	2	1	1	3	1
43	1	1	1	1	1	1	1	2	1
44	1	1	1	1	1	1	1	2	1
45	2	1	1	5	2	1	1	2	1
46	1	3	1	2	1	1	1	3	1
47	1	1	2	3	1	1	1	2	1
48	1	2	2	2	1	1	1	3	1
49	1	1	2	3	1	1	1	2	1
50	2	1	5	1	2	1	1	3	1
51	1	1	1	1	1	1	1	2	1

52	2	1	1	1	1	1	1	2	1
53	2	1	1	1	1	1	1	2	1
54	2	2	1	1	1	2	1	2	1
55	1	1	1	1	1	1	1	2	1
56	1	1	1	1	1	1	1	2	1
57	1	1	4	3	1	1	1	2	1
58	1	1	2	3	1	1	1	2	1
59	1	1	2	3	1	1	1	2	1
60	2	4	5	2	1	1	1	5	2
61	2	3	2	3	1	1	1	5	2
62	1	1	2	3	1	1	1	2	1
63	2	3	2	2	2	1	1	4	2
64	1	1	2	3	1	1	1	2	1
65	2	2	2	2	2	1	1	2	2
66	1	2	2	2	2	1	1	2	1